Exhibit K

IN THE DISTRICT COURT

438TH JUDICIAL DISTRICT

BEXAR COUNTY, TEXAS

JENNIFER RAMIREZ F/K/A JENNIFER GALINDO	)	
Plaintiff,	)	Cause No.
vs.	)	2012-CI-18690
CESAR REYES, JOHNSON & JOHNSON, INC., AND ETHICON, INC.	)	
Defendants.	)	

THURSDAY, MARCH 24, 2016

Deposition of PEGGY PENCE, PH.D., held at Lopez McHugh, LLP, 100 Bayview Circle, Suite 5600, Newport Beach California, commencing at 9:36 a.m., on the above date, before Lisa Moskowitz, California Certified Shorthand Reporter No. 10816, RPR, CLR.

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I N D E X

DEPOSITION EXHIBITS

DEPOSITION EXHIBITS

DEPOSITION EXHIBITS

QUESTIONS NOT ANSWERED

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NEWPORT BEACH, CALIFORNIA
THURSDAY, MARCH 24, 2016, 9:36 A.M.

THE VIDEOGRAPHER: We are now on the record. My name is Jim Lopez. I'm a videographer for Golkow Technologies. Today's date is March 24, 2016, and the time is approximately 9:36 a.m. This video deposition is being held in Newport Beach, California in the matter of Jennifer Ramirez aka Jennifer Galindo versus Cesar Reyes, Johnson & Johnson, Inc., and Ethicon, Inc., Case Number 2012-CI-18690 for the District Court, 438th Judicial District, Bexar County, Texas. The deponent is Dr. Peggy Pence.

Counsel and all present, will you please identify yourselves.

MR. GOSS: Tim Goss for the plaintiff.

MS. SUTHERLAND: Kari Sutherland for Ethicon and J&J.

THE VIDEOGRAPHER: On the line?

MR. GOSS: Did we lose you on the line? Hello? Do you have it muted?

THE VIDEOGRAPHER: Counsel will be noted on the stenographic record. The court reporter is Lisa Moskowitz, and she will now swear in the witness.

PEGGY PENCE, PH.D.,
after having been duly sworn, was examined and testified as follows:

MS. VERBEEK: This is Carol Verbeek. I'm sorry, I lost you.

MS. SUTHERLAND: Okay. We're back.

MS. VERBEEK: Okay.

EXAMINATION

BY MS. SUTHERLAND:

Q. Good morning, Dr. Pence.

A. Good morning.

Q. Would you please tell me your full name?

A. Peggy Jo Clark Pence.

Q. And your address?

A. 1533 Miramar Drive, Newport Beach,

California 92661.

Q. And Dr. Pence, do you still have a company that you work under?

A. Yes, I do.

Q. And what is that company?

A. Symbion, S-y-m-b-i-o-n, Research International, Incorporated.

Q. And is that the company through which you're working essentially for your opinions in this case?

A. That's correct.

Q. All right. And you understand we're here for the Jennifer Ramirez case?

A. Yes, I do.

Q. I'm going to hand you what I have marked as Deposition Exhibit Number 1 which is the notice.

(Exhibit Number 1 was marked for identification.)

BY MS. SUTHERLAND:

Q. And ask you if you have seen that document before?

A. I don't recall having seen this before.

Q. I'm going to bet you have seen a

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document similar to this before.
A. Yes, I have.
Q. All right. Did you bring some stuff with you today with respect to your opinions in this case?
A. Yes.
Q. And what all have you brought with you?
A. I brought my report from April, 2015, and a copy of my supplemental report, dated -- I think it was March 2, 2016, and some copies of Global Harmonization Task Force guidances, and my deposition and trial testimony history.
Q. Oh. Let me see the GHTF's guidances that you brought.
A. My supplemental report is in there as well.
Q. Okay. I may not mark these because I think I got them previously.
A. And the one you have previously is actually more comprehensive. It has some of the older ones as well.
Q. In your great binder?
A. Yes. That I haven't gotten back

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yet.
Q. Golkow has?
A. Yes.
Q. All right. So what I'm looking at you have a GHTF guidance document entitled "Essential Principles of Safety and Performance of Medical Devices," dated November 2, 2012. And a GHTF final guidance entitled "Principles of Conformity Assessment For Medical Devices," dated November 2, 2012. Correct?
A. Correct.
Q. While I'm looking at these dates, I've got a question for you. Am I correct that the GHTF changed to a different organization in 2011?
A. I believe it was 2011 or 2012, yes. The GHTF disbanded, and its work was transferred to IMDRF.
Q. And tell me again what the IMDRF stands for.
A. I know that. Medical Device Regulators -- International Medical Devices Regulators Forum. I believe, and I can just double-check that.

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Q. Yeah. And I really could not remember myself. I was not trying to put you on the spot.
Do you want this back?
A. Yeah, just because I can double-check to make sure I'm giving you the right name for the acronym.
Q. Thank you.
A. I believe it is the International Medical Device Regulators Forum, but I'll check. Yes. International Medical Device Regulators Forum.
Q. Okay. And when did they, I guess, come into existence and the GHTF went out of existence?
A. It was in the 2011 to 2012 time frame.
Q. All right. Was it before the two guidances that you brought with you were promulgated?
A. These -- well, there are other guidances in here as well. These were GHTF guidances. They are on the IMDRF website as current documents with the notation from IMDRF that they are to be considered current

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documents and as time progresses, IMDRF will reissue them as IMDRF documents. But for the present time, they're GHTF documents.
Q. Okay. And those guidance documents, the two that I called out, are dated November, 2012?
A. They --
Q. And I know they're preceded by others.
A. Yes, and they are GHTF documents, though. They are not IMDRF. They were documents that were produced through the GHTF process.
Q. Were they finalized before the GHTF, I guess, for lack of a better term, went out of business?
A. I presume so since they were signed off by GHTRF. So they must have been a part of finalizing their final work. The transition was supposed to have been in 2012. In that 2011/2012 time frame. 2012 is what I have in my report.
Q. Okay. I think you said GHTRF.
A. I'm sorry. GHTF. Sorry.
Q. No worries. No worries. I just

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want to make sure we're straight.
A. It stands for Global Harmonization Task Force.
Q. Got it.
What else have you brought with you today?
A. I think I have one guidance document, MDA guidance document, the device label guidance number G91-1 Blue Book Memo.
Q. Okay. Do you mind if I take a peak at that?
A. Oh, sure.
Q. Okay. And that's obviously referenced throughout your report on your labeling opinions?
A. Yes.
Q. This is a different format for printing than I have seen.
A. I probably didn't do the PDF version.
Q. Did you just print this out yesterday?
A. Yes, last night.
Q. All right. I'm just going to mark it. I think it's the same thing, but I'm

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just going to mark it as Exhibit Number 2.
(Exhibit Number 2 was marked for identification.)
BY MS. CAREY:
Q. I'll hand that back to you.
A. Thank you.
Q. And then did you tell me this binder is just your TVT-O report?
A. Yes, with the exhibits and appendices and a copy of a few references that were footnoted in the -- in my report, at the bottom of my report.
Q. Okay. Do you mind if I just take a peak at that too?
A. Not at all.
Q. And it looks like your references are deposition testimony that you pulled out?
A. And there's a publication as well.
Q. Now, is there a particular reason that you pulled out these references?
A. Those were additional references that were -- there was a report filed for TVT-O in 2014.
Q. Right.

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A. And one in 2015. And I asked my staff to pull out any additional references that I hadn't already pulled out in my 2014 report, and I believe that's what these are.
Q. Okay. So if I'm following correctly, what you've got sort of marked here beginning with reference 217 and skipping some but going up through -- actually 545B are references that are in your 2015 TVT-O supplemental report that were not in your 2014 TVT-O report?
A. Yes. That's my understanding. That's what I asked my staff to do. I've not verified it personally, but that's what I understand that to be.
Q. And are the references that you've got marked here up at the top the footnote numbers?
A. Yes.
Q. All right. I'm just going to call those out for the record so that I'll know what they are and that way I don't think we need to mark another binder of yours.
A. Sounds good.
Q. The first one is reference 217.

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The next one is 218. 219. 224A. 224B. 230. 231A. 231B. 232. 259. 313A. And 545B.
And actually, what I may do to save me even more work is I might get a copy of this at a break just of your references.
A. Okay.
Q. At a break. I will hand this back to you. And then what was the last binder that's underneath there?
A. Just a copy of my report. This is the exhibits and the appendices, and this is a copy of my report.
Q. Okay. And then was this second binder also just a copy of the report?
A. That's the one you were looking at that has the GHTF guidances in it that I brought.
Q. Right.
A. And also my supplemental report.
Q. Okay. Can I see that for one more minute?
A. Sure.
Q. Okay. And then it looks like there's another GHTF guidance in the back

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entitled "Clinical Evaluation," dated May 2007.
A. Yes. And then behind each of the tabs in that binder after the supplemental report are other GHTF guidances.
Q. Oh, okay. I see. I was getting my reports mixed up. This is your -- what I call your MDL supplemental report, but it's your March, 2016, supplemental report?
A. That's correct. That's correct.
Q. With some guidances from GHTF behind it. Which, in fairness, I think, I already have from your previous deposition.
A. Yes.
Q. So I will hand that back to you.
A. Thank you.
Q. And then just because I know Madam Court Reporter has been waiting on it, I'm going to mark what I have as your 2014 report.
A. Okay.
Q. And let you just identify that for me and make sure we're on the same page. I've marked that as Exhibit 3.
///

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(Exhibit Number 3 was marked for identification.)
THE WITNESS: This says Exhibit C on the cover sheet.
BY MS. CAREY:
Q. I marked it with the yellow as Exhibit 3.
A. Okay.
Q. Is Exhibit C your 2014 TVT-O report?
A. I just wanted to be clear on the Exhibit C because there is an Exhibit C -- there is an Appendix C to my report. I just wanted to be sure that it was the entirety of the report and not just the exhibits.
Q. Just the Exhibit C?
A. Yeah. Yes, it appears -- it appears --
Q. Kind of thick.
A. Yes, it's double-sided. I'm just trying to make sure that all the exhibits are there and the appendices. It looks like to be complete, yes.
Q. And then do that same thing for me, if you would, for your supplemental report

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in this case on TVT-O that I've marked as number 4.
(Exhibit Number 4 was marked for identification.)
BY MS. SUTHERLAND:
Q. And it has on the front that same Exhibit 3 down at the bottom.
A. Right. So that Exhibit 3 is overwritten by this sticker Exhibit 4; is that correct?
Q. Yeah. For this deposition, that supplemental TVT-O report is Exhibit 4.
A. Okay.
Q. The yellow sticker.
A. Without going through it page by page, it appears to be the complete report.
Q. Okay. And now I'm going to hand you what I've marked as Exhibit 5, which I understand to be your second supplemental reliance list. Take a look at that.
(Exhibit Number 5 was marked for identification.)
BY MS. SUTHERLAND:
Q. And does that appear to be your reliance list for your TVT-O opinions in the

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Ramirez case, other than what you've got, like, footnoted in your report?
A. It's cumulative. I have other references that are referenced in the reliance list in the report as appendices. So this is --
Q. In addition to that?
A. In addition, yes.
Q. All right. Do you have a reliance list that's dated any later than this one, March 17, 2016?
A. Not at this time, I don't.
Q. Okay. If I were to look at this reliance list and the reports that we've marked so far, including the appendices and exhibits, would that include all of the documents that you're basing your opinions on?
A. To the best of my recollection, as I sit here today, yes.
Q. And the report I'm about to mark, which is your March, 2016, TVT-O supplemental report?
A. Correct.
Q. So let me do that. I'm handing you

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what I've marked as Exhibit 6.
(Exhibit Number 6 was marked for identification.)
THE WITNESS: I do reserve the right to add to this.
BY MS. CAREY:
Q. I'm going to ask you about that.
Now, is Exhibit Number 6 your TVT-O supplemental report dated March 2, 2016?
A. It is the body of the report, but it is missing the exhibits.
Q. Actually, in fairness, it's TVT and TVT-O supplemental report from March, 2016?
A. That's correct.
Q. All right. And you said that had an exhibit to it?
A. Two exhibits.
Q. And I confess I evidently didn't bring the second exhibit, but I've marked as Exhibit Number 7 what had been marked as Exhibit 1 to the TVT and TVT-O supplemental report, which is applicable industry standards; correct?
A. That's correct.
///

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(Exhibit Number 7 was marked for identification.)
BY MS. CAREY:
Q. All right. And I don't know if you remember, but what was Exhibit 2?
A. Exhibit 2 is a tabular presentation of the numbers of MDR reports through 2015 for a number of manufacturers and certain products of those manufacturers.
Q. That's right. And do you have a similar exhibit attached to your April, 2015, report?
A. Yes. I believe it's Exhibit 3, if I recall correctly. Yeah.
Q. And you may not know because you don't have it in front of you. Is it the same exhibit?
A. No. It's different. The Exhibit 3 includes -- that you're looking at includes, I believe, only stress urinary continence.
Q. Correct.
A. And the one that is included in the supplemental report from March 2016 is updated through 2015, and it also --
Q. Has prolapse products?

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A. It also has the pelvic organ prolapse products. I do believe I brought a copy of that. I have it here.
Q. Okay. So looking at what we've marked as far as your reports and exhibits to reports, do those encapsulate, first of all, your opinions in this case?
A. Yes.
Q. All right. Do those items that I've marked, not the deposition notice but otherwise up to Deposition Exhibit Number 7, would those all encapsulate the bases or the documents that you've relied on for your opinions in this case?
A. Yes.
Q. Okay. You mentioned something about reserving the right to supplement your numerous reports. As you sit here today, do you have an intention to supplement any of your reports related to TVT-O?
A. At the present time, I'm not anticipating a supplement. If new information becomes available or after reviewing reports of other experts, it's appropriate for me to supplement my reports,

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then I reserve the right to do that.
Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in your head of things you already want to supplement?
A. Not at this point in time.
Q. Okay. And obviously, if you did that, you'd let your counsel know, and he'd let us know.
A. Of course.
Q. As you sit here today, other than I'm sure reviewing your reports, do you have any other work that you intend to do in this case?
A. Can you clarify?
Q. Yeah. Do you have any other charts you intend to put together for this case, any other depositions you intend to review, essentially any other work you intend to do in this case other than obviously reviewing your reports and preparing for testimony?
A. If there are other reports of experts or other reports that are applicable to the case that I've not yet seen or reviewed, I perhaps would review those. If

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there's anything new that's presented, I would review that.
Q. Have you asked for anything to review in this case that you haven't already been given?
A. To the best of my recollection, as I sit here today, no.
Q. Did you review -- well, first of all, the plaintiff in this case is Jennifer Ramirez; right?
A. Yes.
Q. Have you reviewed her medical records?
A. I've reviewed not all of her medical records in their entirety but an overview of her medical records through depositions that I've reviewed of her care.
Q. Okay. Let me make sure I -- well, do you have a listing of items specific to this case that you've reviewed? You know what I'm talking about? The plaintiff deposition? In-plainor deposition?
A. I would have to look at the reliance list to see if those are included.
Q. Do you mind? Let's just take a

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minute. I just want to be sure I know for this particular case what you've looked at.
A. Okay.
Q. And I think I've got it on the very last page of your March 17, 2015, reliance list. Is that what you're looking at? That's what you're looking at.
A. Yes.
Q. All right. Now --
A. There is one addition.
Q. Okay. What's that?
A. And that is Jennifer Ramirez most recent, if I recall correctly, as I sit here today, there was a third deposition, and I did -- I don't recall the -- it post dated the August 2014.
Q. She's been deposed three times in this case?
A. I think so, yes.
Q. And you reviewed that third deposition?
A. I did.
Q. All right. Anything else that needs to be added to your case-specific reliance list?

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A. Not as I sit here today.
Q. And when you say that you had reviewed medical records, would those have been the exhibits to the doctor's deposition?
A. That's correct.
Q. All right. Does your reliance list that I marked as Exhibit Number 5 include all of the medical literature that you've reviewed, or is there a separate listing of the literature?
A. There is literature in here. There's also literature in my prior reports that's in my reliance list.
Q. As an attachment to your report?
A. Exhibit B in my reports includes reliance list. So there's medical and scientific literature included there.
Q. Okay.
A. And literature is also footnoted as -- referenced as footnotes throughout the body of the report as well, and then there's literature that is included in the March 17, 2016, reliance list as well.
Q. All right. Is there literature

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that you've reviewed that would be listed elsewhere other than those places you just told me about?
A. The Appendix C to my report includes summaries of certain literature. In order to -- I would have to -- ideally, everything that's in Exhibit -- I'm sorry, Appendix C to my reports would be included in my reliance list, but to verify that, I would need to sit down and do a double-check.
But if you look at Appendix C to my reports, Appendix B to my reports, which is the Appendix B being the reliance list and the March 17, 2016, reliance list and the references that are throughout my report where literature is cited --
Q. You think that might cover the waterfront?
A. I'm hoping so, yes. It should, yes.
Q. The reason I'm asking is there a file that you keep at home specific to pelvic mesh that might include additional items other than what we've got on all your

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reliance lists and your appendices?
MR. GOSS: Be careful. This is where Hilary Clinton got in trouble.
MS. SUTHERLAND: Do you have an email server for all the secret email of plaintiff counsel -- strike that.
Read back my original question.
(Record read by the reporter as follows: The reason I'm asking is there a file you keep at home specific to pelvic mesh that might include additional items other than what we've got on all your reliance lists and appendices?")
THE WITNESS: There are a large number of publications that are cited in the various documents that we've just been -- or that are included in the various documents that we have just been discussing. There may be other documents that I have reviewed more recently that -- looking at certain update -- you know, updated reports coming out routinely that may not have made it into the reliance list at this point in time because I do my best to stay current, but I'm becoming aware of

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new literature all the time.
So it may be that there are publications that have not yet made it into a reliance list that I do have in my files at home. I try to be as comprehensive as possible, but as you can see --
BY MS. SUTHERLAND:
Q. It's extensive.
A. -- it's extensive.
Q. If there was new stuff, are you talking about things that might have come out within the past six months or so that might just not have made it to the list yet?
A. Yes. Or even within the last year that I just may not have had an opportunity to review yet or am in the process of reviewing.
Q. With respect to TVT-O, is there any piece of literature that's come out within -- I'm going to limit it to six months -- that was of significance to you and your opinions in this case?
MR. GOSS: I'm sorry. Can you say that --

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THE WITNESS: Do you want me to restate it?
MR. GOSS: Yes.
MS. SUTHERLAND: Yeah.
BY MS. SUTHERLAND:
Q. Is there a piece of medical literature, peer-reviewed publication, that's come out in the past six months specific to TVT-O that is of significance to you in your opinions in this case?
MR. GOSS: Objection. Form.
THE WITNESS: You're talking about solely scientific literature?
BY MS. SUTHERLAND:
Q. Yes, ma'am.
A. There continues to be. I can't speak to the six months specifically without looking back at literature and confirming it's within the last six months. There continues to be literature published that substantiates my opinions.
Q. Okay. Give me an example -- the reason I'm asking is just to see if there's something that has come out recently that might not be on your reliance list that

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you're thinking of today.
A. For example, I believe it's Dr. Ross and the publication that's five-year results of a study that she had done with obturator versus -- if I recall correctly, it wasn't the Ethicon product but another obturator -- transobturator sling versus the retropubic sling approach. Her publication.
That, I've just recently reviewed in the last couple of weeks. Things of that nature. But nothing that has changed my opinions but provides further support for my opinions.
Q. And do you do, like, a weekly PubMed search to find new literature?
A. No. I don't do it weekly.
Q. How often do you do a literature search to make sure you're getting the most up-to-date literature that might address pelvic mesh?
A. Periodically. I don't have a set schedule but periodically.
Q. When's the last time, for instance, that you did a PubMed search?

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A. Probably within the last two months.
Q. And do you do something besides PubMed?
A. I do ask counsel if there's any new literature that they're aware of as well that would be important for me to review. So that's -- I do look for, for example, Cochran reviews, things of that nature.
Q. Now, I had limited my question to literature, and you had specifically asked me about that. Is there another document that's come out recently specific to your opinions on TVT-O that you were thinking of?
A. The FDA -- and unfortunately, I don't have the binder because it's one of the ones that's with Golkow that I don't have back, but there was an advisory committee meeting in February of this year to discuss and make recommendations whether or not to reclassify the instruments that are used in the insertion of the medical devices in stress urinary incontinence devices, for example, to reclassify those from Class 1 to Class 2.

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Q. And was that a panel meeting?
A. Yes, it was.
Q. And were there recommendations made by the panel?
A. Yes. If I recall correctly, and I wish I had that document with me, but if I recall correctly, the recommendation was to reclassify those insertion instruments, those types of medical devices as Class 2.
Q. All right. Now, how would that, if it would, impact the TVT-O and your opinions on TVT-O?
MR. GOSS: Objection. Form.
THE WITNESS: They were still reviewed, the instruments for insertion for TVT-O were included in the review of the -- in the 510(k). So they were included in the 510(k), reviewed for clearance of the TVT-O.
But the instruments by themselves had previously been classified as Class 1. When they're reviewed as a part of the 510(k), then they're reviewed. Obviously, they were included in the 510(k) submission as a

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Class 2 device. They were reviewed, I should say, in the same framework as a Class 2 device.
BY MS. SUTHERLAND:
Q. Okay. Let me make sure I'm on the same page with you for that.
For the instruments that are within the TVT-O kit --
A. That's correct.
Q. -- for insertion, were those instruments already reviewed as Class 2 because they were part of the 510(k) submission on TVT-O?
A. Yes. Yes. But if they were -- if they were to be manufactured separately outside of a kit, they would no longer be considered Class 1. They would be considered a Class 2 as part of the 510(k).
Q. Well, actually, have they been reclassified?
A. No. There's a recommendation. As we know, that takes -- that's a process.
Q. Some time.
A. It takes some time. But if, in fact, FDA makes a determination that they

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will reclassify those instruments and they reclassify them as Class 2, then they become, if I recall correctly, the recommendation would be that they would require a 510(k) submission.
Q. Okay. Does Ethicon sell the instruments separately? Do you know?
A. As far as I know as regards to TVT-O, they're sold in the kit.
Q. In the kit.
A. Yeah.
Q. All right. So just with respect to the TVT-O, would I be correct that even if those instruments were reclassified as Class 2, would that impact TVT-O?
A. I think the real point is that the instruments-- if I recall correctly -- do you have a copy of the 510(k)?
Q. I don't. He may.
A. If I recall correctly, I'd have to look specifically in the TVT-O 510(k), but many times you will see in the 510(k) that the instruments are discussed as Class 1 devices by the manufacturer. They are reviewed -- when it's -- when they are

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submitted as a part of a kit, obviously, a 510(k) has been submitted. The FDA is looking at the instruments as a part of the 510(k).

So even though they may have been on their own considered Class 1 devices, the FDA is looking at them within the framework of the context of a 510(k). I think the significance of the finding or the recommendation, I should say, of the advisory committee is that the instruments require more than general controls, if they require special controls to provide a reasonable assurance of safety and effectiveness which is the criteria to define a Class 2 device, that there are -- that the instruments themselves, safety and effectiveness issues need to be addressed for the instruments as well.

Q. And so would Ethicon need to do something different with the TVT-O if those instruments got reclassified?

A. At this point in time, all I've seen that's been published that I've seen is the recommendations from the advisory

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committee. Since these were marketed as part of the kit, I don't anticipate that, but I don't know until we see what FDA does, unless they were to be marketed separately from the mesh, for example --

Q. Okay.

A. -- then they would require a separate 510(k). But until FDA makes a determination --

Q. We don't know yet.

A. -- we don't know yet. And it might be that FDA might come back and say, "We'd like to see more information about the insertion tools."

Q. Or they may not.

A. Or they may not. Exactly. It's too early to tell, but certainly that was an important advisory committee meeting in the context of the TVT-O and other devices such as this.

Q. Did you attend the advisory committee meeting?

A. No, I didn't.

Q. I'm sorry. You shook your head yes, but you said no.

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A. Oh, I'm sorry.

Q. Were you asked by FDA to be on the advisory panel?

A. No.

Q. Was there more than one advisory panel or just one?

A. There was -- for this, my understanding it was the latter part of February, and there was, to my knowledge, as I sit here today, there was one.

Q. Okay. And do you know which panel it was? And I'm sorry I don't have the document in front of me. I just don't know if you recall.

A. Yes. I believe it was -- had to do with urology, but I would have to look it up. As I say, it's in the binder that I still don't have back.

Q. You keep throwing that out there. Come on. We'll get it back.

Let me ask you a follow-up on something you just said. As I understand it, you said the instruments had been Class 1, and Class 1 are devices for which general controls are sufficient --

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A. Yes.

Q. -- to demonstrate safety and efficacy.

A. Correct.

Q. All right. And then Class 2 devices, such as the TVT-O, are devices where you need not only the general controls, but there are special controls in order to demonstrate safety and efficacy; correct?

A. That's correct.

Q. All right. What are the special controls applicable to, for instance, a device like the TVT-O to demonstrate safety and efficacy so that the FDA can clear it?

A. It varies by device. For example, there can be a special guidance documents or various -- various procedures that are required. There can be certain types of -- in some cases, certain types of labeling requirements. There are some types of post-market surveillance, certain types of special controls. There is the guidance document, as you know, for the surgical meshes.

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Q. I was going to ask, is that the '99 surgical mesh guidance that you're talking about?
A. Yes. That would be one.
Q. That would be one example of a special control applicable to TVT-O?
A. That's correct.
Q. All right. Are there others applicable to TVT-O?
A. I would have to look at the classification index, for example, certain standards like the ISO standards, voluntary consensus standards, those can be -- certain types of consensus standards. I need to look at the classification regulation and refresh my memory on that as to whether or not there are any of those cited. The key one, as I recall, is the 1999 guidance document.
Q. Okay. And I'll be candid with you. I'm not aware of another special control, but I didn't know if you might know one off the top of your head.
A. Well, in the guidance, in the March 1999 guidance, I don't have a copy

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here in front of me, but it discusses biocompatibility, for example, and the ISO standard. So by inference, some of the standards such as ISO standards are addressed by the guidance document.
Q. Okay. And the ISO standards that are referenced in that surgical mesh guidance, am I correct that those have been specifically adopted by FDA?
A. I'm sorry. Say again.
Q. Sure. The ISO standards that you're referencing from the '99 surgical guidance on surgical mesh, have those been specifically adopted by FDA?
A. FDA actually has its own guidance document where it discusses the ISO standards. So that is, to the best of my recollection, those have been adopted, but it has its own -- generally speaking, they have been adopted, but FDA also has its own guidance document that addresses the ISO 1099-3 standard for biocompatibility.
Q. Okay. And then I'm thinking of another ISO standard for some reason. Is there a 141 --

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A. 55.
Q. 55? I was thinking 77. Is it 14155? Which ISO standard is that?
A. That is the clinical investigations. Which one are you --
Q. I was thinking of a different one. We'll come to it. All right. I got off my outline as I tend to do.
A. No worries.
Q. Which lawyers are you working for in this case?
A. Mr. Goss.
Q. And have you worked for Mr. Goss before?
A. I have.
Q. About how many cases have you worked with him on?
A. For mesh?
Q. I'll start with for mesh.
A. To the best of my recollection --
Q. You have a list.
A. I have a list. I can actually verify my memory. At this point in time, it appears to be five.
Q. Okay. And I'm glad you pulled that

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out. I'm going to mark that actually as Exhibit 8, and I'm marking as Exhibit 8 your deposition and trial testimony; is that correct?
A. Yes.
(Exhibit Number 8 was marked for identification.)
BY MS. SUTHERLAND:
Q. All right. Now, does this list, your deposition and trial testimony, it looks like from October of 2009?
A. I'm sorry. What was that question again?
Q. Does this list, your deposition and trial testimony, Exhibit 8, as of October, 2009?
A. Yes. That was my first deposition that I've ever given.
Q. And that's up through, it looks like, December 2015?
A. Yes. For trial testimony. And deposition testimony is there as well. So my deposition from two weeks ago is not included --
Q. Right.

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A. -- yet.
Q. Are there -- so it looks like your deposition testimony ends in November of 2015 on Exhibit 8.
A. Yes.
Q. Is the deposition that I did of you two weeks ago the only deposition that you've given to date in 2016?
A. Can I just take a look at that?
Q. Oh, sure.
A. Time goes so quickly. I have to stop and think.
Q. Yeah, I know. We're just in March.
A. I know. To the best of my recollection, as I sit here today, that's correct.
Q. Okay. Just the one I did two weeks ago?
A. Yes, that's correct.
Q. You can keep that in front of you. I'm going to ask you a few more questions while we're on the topic.
In looking at Exhibit 8, are you able to tell me how many times you've testified at trial in a pelvic mesh case?

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A. I believe it's nine but just let me check that. Yes, nine.
Q. Okay. Nine trials?
A. Nine trials.
Q. For pelvic mesh?
A. Yes.
Q. And how many mesh manufacturers has that involved?
A. Three.
Q. And who are they?
A. Ethicon, Boston Scientific, and Bard.
Q. All right.
A. CR Bard.
Q. And which products have you testified at trial for?
A. That would include for Bard, the Align. Discussion about Avaulta came up, but it was principally Align.
Q. Is Align a sling or a prolapse?
A. It's a sling.
Q. Okay.
A. And for Ethicon, it's included Prolift, Prosima, TVT Abbrevo, TVT-O.
Q. What trial was that?

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A. TVT-O?
Q. TVT-O.
A. Batiste. Batiste. I think that's -- those are the products for Ethicon, and then for Boston Scientific, it would have been Obtryx.
Q. Is that a sling?
A. Yes. And Pinnacle.
Q. Is Pinnacle a sling?
A. No.
Q. It's a prolapse?
A. It's a pelvic organ prolapse device.
Q. All right. So for sling cases where you've testified at trial, am I right that it's the Align, the TVT-O, Obtryx, and the Abbrevo?
A. Yes. And also for Boston Scientific and the Scherer trial, it also included the Solyx.
Q. Is that a sling?
A. Yes. It's a single-incision sling.
Q. Okay. And that was a trial?
A. Yes.
Q. Now, have you given deposition

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testimony in cases involving additional products for pelvic mesh?
A. Yes.
Q. Can you tell me what those are?
A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the Prefix, which is a sling.
And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I think the only other sling about which I have given deposition testimony is TVT from Ethicon.
Q. Okay.
A. And then we've already addressed Bard.
Q. Okay. So no additional products in deposition testimony for Bard?
A. No. As I mentioned, I had an Avaulta report which was the focus of the -- the focus of the deposition was Align, but their Avaulta was also discussed, and my report for Avaulta was also incorporated in that deposition as an exhibit.

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Q. And is Avaulta a sling?
A. No. It's an pelvic organ prolapse device.
Q. Okay. I'm just trying to make sure I've got all the sling devices where you've offered deposition or trial testimony, and let me see if I've got them.
A. Okay.
Q. I have Align, TVT-O, Obtryx, TVT Abbrevo, Solyx, Prefix, and TVT.
A. Yes.
Q. Okay. And those are from three different manufacturers?
A. That's correct.
Q. All right. Does AMS also make a sling product or they did?
A. Yes.
Q. All right. Other than -- have you offered any opinions in any AMS case?
A. No, I have not.
Q. Okay. Is there another mesh manufacturer that makes a sling?
A. There are other manufacturers, yes, that make slings. Those --
Q. Have you reviewed any of those

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manufacturers' documents?
A. No, I have not.
Q. All right.
A. Other than in the context of doing my report for the products that we've discussed, I do do research and go online and look at 510(k) summaries of safety and effectiveness for certain devices.
I've obviously looked at MDR reports, which are included in a number of my reports. So publicly available information or information that might be in some of the records that have been produced during discovery for the various cases.
I may have reviewed information about some of the slings or press releases or information that's publicly available, but in terms of have I worked on other manufacturers' sling products in the context of reviewing confidential documents to -- and arrive at opinions, no, I have not done that.
Q. Have you reviewed that you can recall any IFUs for slings other than the seven that you and I have talked about?

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A. No.
Q. Okay. I'm not meaning that to be a trick question. For instance, like if a sling was a predicate for one of these other products, typically that IFU is within the 510(k); right?
A. Yes. If you're talking about that, yes. In reviewing the 510(k)s. I'm sorry. I understood your question to be separately.
Q. Yeah, and I'm not trying to, you know, trick you up on that. But as you sit here today, for instance, in addition to these seven, would you have reviewed the ProteGen IFU as it's the predicate for TVT?
A. I don't recall. I would have to look back at the 510(k) to see if the ProteGen IFU was included.
Q. Okay. I think it was, but as you sit here today, you don't recall?
A. I would have reviewed it if it was, yes.
Q. Do you recall any other IFUs that might have been within the 510(k)s of these seven other products that you might have reviewed?

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A. The predicate -- the predicate devices for those products.
Q. Okay. I mean, do you recall what they were?
A. Well, certainly, TVT-O's predicates were the TVT, the TVT device.
Q. Yeah. But you reviewed that because that's one of your products; right?
A. Exactly. And then similarly -- let me just take a moment. So --
Q. Can I tell you why I'm asking that?
A. Sure. Sure.
Q. I'm just asking if there's one that stands out to you that you know you reviewed that's not one of these seven sling products that you and I have already talked about.
A. No. Many of them, as you know, they all go back -- they go back ultimately to the ProteGen.
Q. Right.
A. Ultimately in the hierarchy and the substantial equivalence decision tree, is they typically all go back to the ProteGen because then TVT relied on the ProteGen for its clearance, and then some of these later

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devices reference -- including TVT-O references the TVT.

And the advantage I would have -- for example, the Advantage meshes, I would have reviewed their -- for Boston Scientific, I would have reviewed their IFUs.

Q. Is Advantage a sling?

A. Yes. Advantage and Advantage Fit. I would have reviewed those.

Q. All right. And Advantage Fit?

A. Yes.

Q. Any others that kind of pop in your mind?

A. Without checking back, I can't recall for sure. I may have -- I may have looked at Monarc or --

Q. SPARC?

A. Pardon me?

Q. SPARC?

A. SPARC possibly. MiniArc. Without checking back, I can't confirm, but I may have looked at those.

Q. Okay. All right. And so now as we sit here today, we've got one, two, three,

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four, five, six, seven, eight, nine slings where you think you've reviewed the IFU for those slings?

A. Yes.

Q. All right. Now, out of those nine, did you ever determine that the IFU was adequate?

A. No. I found them all to be inadequate.

Q. All right. Is there any IFU for a sling product today that you believe is adequate?

A. There are some that are improved over what they were, but they're still -- for example, in the --

Q. Can I get a yes or no to the question first? Are there any IFUs for a sling product today that you believe are adequate?

A. Well, as we already mentioned, I have not reviewed all sling IFUs.

Q. The ones you have.

A. So I can only speak to the ones that I have reviewed.

Q. Right.

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A. The ones that I have reviewed, and I have not -- for some of these products where I have not done an updated report, if there have been changes since I last opined about it, I may not have seen any updates to labeling to the IFUs.

For those that I have seen, for example, the TVT-O, there are improvements, and some of the information that I, in fact, included in my reports going back to even, if I recall correctly, 2013, information that I documented then that should have been included in the IFU has since been included.

Q. Is it adequate?

A. No. And as I stated in my supplemental report, which we've marked as Exhibit 6, there are still -- there is still missing information as regards safety and risk even in the updated 2015 IFU for TVT-O.

Q. Okay. So to get a clean question and answer, if I could, is there any IFU that you've reviewed, even up to the present day, that you consider adequate?

A. No.

Q. Okay. And I don't know if I -- I

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was talking about sling IFUs. You knew that; right?

A. Yes. Yes.

Q. All right. What is your hourly rate for work?

A. $500 an hour.

Q. Is that for deposition and review of documents?

A. Yes.

Q. All right. Are you charging 500 an hour today?

A. Yes.

Q. Do you have a -- if you're here all day, do you have an amount that you charge for the entire day that's different than your hourly rate?

A. No.

Q. Did you meet with plaintiff counsel before today in order to prepare for your deposition?

A. Yes.

Q. All right. What did you do when you met with him?

MR. GOSS: Are you asking her what we talked about?

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BY MS. SUTHERLAND:
Q. What did you review?
MR. GOSS: What did you review? Okay.
THE WITNESS: We talked about GHTF.
MR. GOSS: Wait a minute.
THE WITNESS: Oh, sorry.
BY MS. SUTHERLAND:
Q. Keep going, though.
No, what documents did you review?
MR. GOSS: Listen, I'm going to instruct you not to answer that question. There's an agreement, as I understand it, that we're not getting into each other's discussions with experts beforehand and what we showed experts beforehand. That's my understanding. If you want to --
MS. SUTHERLAND: I'll check at a break because I don't know.
MR. GOSS: At a break, maybe if you want to check but --
MS. SUTHERLAND: Right now you're instructing her?

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MR. GOSS: Right now I'm instructing her not to answer because I certainly know there's agreements about, you know, drafts reports and things like that.
MS. SUTHERLAND: I'm not asking about draft reports. I was asking her what she looked at to prepare for her deposition today, and if you're instructing her not to answer that --
MR. GOSS: I'm instructing her not to answer. I object to foundation and --
MS. SUTHERLAND: -- then I'll ensure that we're on the same page.
MR. GOSS: -- I'm instructing her not to answer.
BY MS. SUTHERLAND:
Q. Well, did you review any documents to prepare for your deposition today?
MR. GOSS: Same objection.
MS. SUTHERLAND: Are you instructing her not to answer that?
MR. GOSS: Instructing Ms. Pence not to answer.

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BY MS. SUTHERLAND:
Q. How many times did you meet with counsel to prepare for your deposition today?
A. Just once.
Q. And when was that?
A. Yesterday afternoon.
Q. And how long did you all meet?
A. Two-and-a-half to three hours.
Q. And where did you meet?
A. Here.
Q. How much time have you put into the Jennifer Ramirez case?
A. In anticipation of your asking me that, I attempted to evaluate that last night. As you know, there's a lot of crossover between the reports and what's relevant to her case as well. Specific to her case and, as you know, also this case has been continued a couple of times and, in fact, preparing for deposition on another occasion and it ended up being canceled towards the time that it was supposed to occur, if I'm recalling correctly as I sit here today.

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So I went back and looked at that time, and to the best I'm able to estimate it at this point in time, it was approximately 107 hours specific for this case.
Q. Okay. Now, would that include, for instance, time spent on your supplemental TVT-O report from March, 2016?
A. No.
Q. All right. So that would be -- since this is now part of your opinions in this case, would that be additional time?
A. Yes.
Q. Do you know how much that would be?
A. I think at the last deposition that I included the preparation for this in the -- in a total of time that I gave you because I put two supplemental reports together in close proximity, and I didn't separate out how much time for this report specifically. I haven't billed for that yet; so I can't give you a specific answer.
Q. Have you submitted any invoices for the Jennifer Ramirez case?
A. No.

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Q. Are you hoarding them up to give them one painful invoice at the end?
A. I often -- I often wait until a case is finished or a project is finished and bill at the end. That's one way that I frequently bill.
Q. And you keep up with your hours how? Since this case has been going on for so long, how do you keep up with your hours on it?
A. They get recorded -- ultimately, they get recorded from -- I document my hours, and then they get put into QuickBooks.
Q. Okay. And have other people at Symbion billed on the Jennifer Ramirez case?
A. Yes.
Q. And are you including their time in your time when you tell me about 107 hours?
A. No. That's my time.
Q. All right. Do you know how much time -- first of all, let me ask you this: How many other people have worked on the Jennifer Ramirez case for you?
A. Again, because this has been

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ongoing for probably a couple of years, if I recall correctly, I would need to go back and just double-check, but I would anticipate that or I would believe that at least -- at least three to four other people have worked on this case at one point in time or another.
Q. Okay. You don't know, like, a ballpark of their hours?
A. No. I didn't look at that.
Q. Okay. Is that something you could look at?
A. Yes.
Q. Do you know overall how many hours you've put in to the pelvic mesh litigation against Ethicon and J&J?
A. No.
MR. GOSS: Objection. Form.
THE WITNESS: Not without going back and tallying it.
BY MS. SUTHERLAND:
Q. Okay. Do you know how much money you've billed for in the pelvic mesh litigation against Ethicon and J&J?
A. Again, not without going back and

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actually totalling it.
Q. Do you know if it's more than a million?
MR. GOSS: Objection. Form.
THE WITNESS: Not without going back and tallying it. I don't think it's more than a million, but I wouldn't want to rely on that with great fact in doing my calculations.
BY MS. SUTHERLAND:
Q. Okay. Do you have that information available in your QuickBooks?
A. Yes.
Q. All right. And so that's -- would it be an undue burden to find that out for me?
A. Sure. I can find that out.
Q. Mean it would not be an undue burden?
A. No. I'm sorry.
Q. No worries.
And when I talk about the pelvic mesh litigation against Ethicon and J&J, you know I'm talking about both your work on the prolapse products as well as the sling

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products?
A. Yes. Yes.
Q. Okay. Do you know how many documents you've reviewed in the pelvic mesh litigation for Ethicon and J&J?
A. Thousands.
Q. Okay. Do you know how many documents Ethicon and J&J have produced in the pelvic mesh litigation?
A. I'm sure it's millions. As you can see from the size of the Appendices B and the reliance list that we've just discussed today, over the period of time, I'm sure I've reviewed over the period of since 2012 working on Ethicon mesh litigation, when I say thousands, I'm not talking about a couple of thousand. Huge numbers of documents and huge numbers of pages.
Q. If Ethicon and J&J have produced nearly 25 million pages of documents in this litigation, do you know, just ballpark, what your number of pages would compare with that?
MR. GOSS: Objection. Form.
THE WITNESS: I don't know what

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percentage. I know -- you can see from the volume the size of the -- I'll just reiterate what I said a few moments ago, you can see from the volume of the reliance list the numbers of documents that have been reviewed.
BY MS. SUTHERLAND:
Q. Do you think it's been a million pages?
A. It may be. I just don't have a number to give you. I can only say it's been a very large volume of documents, and I have cabinets full of binders as well as what I have archived electronically.
I have multiple cabinets full of binders of TVT and TVT-O and Prolift and Prosima and TVT Abbrevo.
Q. And those multiple binders you're talking about would be on the exhibit lists, the reliance lists that we've marked today?
A. Yes. Yes. Because I'm still old school enough that I like to use hard copy as well as electronic copies.
Q. Do you know that you have not reviewed all of the documents produced by

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Ethicon and J&J in this litigation?
MR. GOSS: Objection. Form.
THE WITNESS: It's my understanding that I wouldn't have reviewed all of the documents that have been produced.
BY MS. SUTHERLAND:
Q. Okay.
A. But the ones that are relevant to my opinions, I have reviewed.
Q. Do you know what percentage of your income has come from expert consulting work in the past five years?
A. I haven't averaged it over the last five years. I have provided testimony on that before in previous -- in previous depositions and at trial, if I recall correctly. Certainly in depositions.
When I first began product liability litigation work, I was first contacted the latter part of 2008 and really began doing work in 2009 to any great extent. And it's progressed from -- to the best of my recollection as I sit here today, I think what I've indicated is it may have

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been around 5 percent or less in 2008, and then over the period of time, it moved to maybe 20 percent. And because, as we were discussing earlier, the mesh litigation is so large, and there's been -- it's at a point in time when there are so many cases going to trial and so much happening in the litigation that my time involved in litigation work has certainly increased over the last -- over the last couple of years.
I think my testimony -- I may have said maybe greater than 50 percent, and it depends really on the -- what's going on, what's happening at any particular time. Sometimes it's higher than that. Sometimes it may be less than that.
I'm teaching, and I'm getting ready to start class again. When I'm teaching, that takes up a large part of my time, and I work on other projects as well. So it really depends on what's happening.
Sometimes it -- in certain weeks, it may be all encompassing. Almost. Not entirely. But in other weeks, I'll be focused on teaching and not do anything on

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the litigation side.
Q. Do you think it was over 50 percent last year?
A. Yes. I think that's fair.
Q. All right. So far this year, has it been over 50 percent?
A. So far this year, yes.
Q. Okay. Do you know by how much over 50 percent?
A. No. I haven't done a calculation.
Q. And has your work been for plaintiffs?
A. Yes.
Q. Consistently since you started consulting in 2008?
A. No.
Q. All right. When did it become consistent for plaintiffs?
A. Without checking back the dates, I can't give you an exact date. The point is I evaluate each case. If what you're asking is do I only work for plaintiffs, I evaluate each case, and I take -- I don't take every case that I'm asked about.
So I evaluate to see if whether or

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not the opinions that I would be -- are the allegations that are being made based on what I can review are something that I believe that I could support, that my opinions based on what I review would be consistent with what counsel -- counsel's claims are.

If they're not, I don't take the case. I don't --

Q. In the -- I'm sorry. Were you done?

A. I was just going to say I'm very -- I will not testify or take any case if my opinions are not 100 percent consistent with the claims that are being made.

If I review those, and I think that there's an issue, I don't take the case. I have to believe and stand behind my opinions.

Q. Okay. In the past five years, have you taken a case for a defendant?

A. Yes.

Q. Okay. Who was that?

A. It was for -- it was a pain -- it was a pain pump case, and it was --

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MR. GOSS: Can we take a bathroom break after this line of questioning?

MS. SUTHERLAND: Yeah, yeah. Time flies.

MR. GOSS: Too many Diet Cokes this morning.

THE WITNESS: It was a contractual issue between one pain pump manufacturer and DJO.

BY MS. SUTHERLAND:

Q. Okay. Let me change my question.

A. Okay.

Q. Because I'm really just interested in product liability cases where a plaintiff is alleging they got hurt.

Have you worked for a defendant in a product liability case in the past five years?

A. No.

Q. All right. Have you turned down a pelvic mesh case that you were asked to review?

A. Not a pelvic mesh case, no.

Q. All right. So every pelvic mesh

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case that you've been asked to opine about you, in fact, have opined about. Is that fair?

A. After reviewing the information and seeing whether or not my opinions would be consistent with the claims that -- yes.

Q. Okay. So the answer to my question is yes? Every pelvic mesh case you've been asked about, to opine about you have, in fact, opined about? Is that fair to give me a yes or no?

A. To the best of my recollection as I sit here today, yes.

Q. Okay.

MS. SUTHERLAND: Let's, yeah, let's take a break.

THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately 10:53 a.m.

(Recess taken from 10:53 a.m. to 11:01 a.m.)

THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 11:01 a.m.

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BY MS. SUTHERLAND:

Q. Dr. Pence, sooner or later, we're going to get into your opinions in this case.

Have you published any of your opinions that you're intending to offer in this case?

A. No.

Q. Have you ever spoken with any scientist about the opinions you intend to offer in this case?

A. If you can clarify your question, I am a scientist; so I'm not sure what the question is.

Q. Well, other than talking to yourself, have you talked with any other scientist about your opinions in this case?

A. I've not talked with any other scientists. I've certainly read deposition testimony. I've read expert reports. I've read internal documents of Ethicon's own scientist.

Q. Have you talked -- and I'm talking about talked. I understand what you've read and what's on your reliance list. Have you

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talked with any engineers about your opinions in this case?
A. No, I have not.
Q. All right. And then other than physicians that are paid by plaintiffs to be expert witnesses, have you talked with any physicians about your opinions that you're intending to give in this case?
MR. GOSS: Objection. Form.
THE WITNESS: I haven't talked with physicians about my opinions in this case, including those, as you noted, that are paid by plaintiffs for this particular case. My opinions are based on my review of the deposition -- a number of depositions of both Ethicon employees as well as the depositions that are referenced in the reliance list that we went through earlier, internal documents, standards, and an integration of all that information and analysis to arrive at my opinions.
BY MS. SUTHERLAND:
Q. Right. My -- with all due respect, I'm going to move to strike.

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But my question is: Just did you talk with any physicians about your opinions in this case?
A. No.
Q. And, obviously, you've offered opinions on the adequacy of IFUs in pelvic mesh cases, including this one; correct?
A. Yes, that is correct.
Q. All right. Now, as I understand it, you have talked with plaintiff expert physicians about pelvic mesh IFUs; is that right?
A. Can you clarify your question?
Q. Yeah. I thought you had testified in one case earlier that you had talked with Dr. Rosenzweig about an IFU in a pelvic mesh case.
Do you recall talking to him about an IFU?
A. No. I think, to the best of my recollection as I sit here today, what you may be referring to is I was asked whether I had spoken to any physicians about pelvic mesh issues, and I would have mentioned Dr. Rosenzweig and Dr. Margolis.

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Q. Yeah.
A. But I didn't talk with them about what should be in an IFU specifically, no.
Q. Okay. Let me ask it cleanly.
Have you talked with any physicians about the opinions you have expressed in the pelvic mesh litigation about IFUs?
A. As I understand your question, no.
Q. Okay. All right. Is it fair to say that the opinions that you're going to opine about in the Jennifer Ramirez case you developed specifically for litigation?
A. Let me answer that this way: I was asked to review the relevant documentation and deposition testimony related to the clearance and marketing of the TVT-O and whether or not Ethicon met the standard of care for not only preparation of the IFU but for testing, its responsibilities for post-market surveillance, and so forth.
As a part of being a regulatory affairs professional, if you look at -- and I'm a RAPS fellow, and the reason I bring that up is because there is a level of experience in order to achieve that level

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that one must meet, and a part of that is being able to evaluate package inserts, instructions for use, labeling, and know what goes in labeling. That's part of my credentials.
So I evaluated all of the information that I -- as I mentioned, deposition testimony, internal documents, what the company knew or didn't know, scientific and medical -- what the company knew or didn't know based on their own internal documents, or what they should have known, scientific literature, the publicly available MAUDE database, not only for its own products but for other products where complications and other safety issues have been reported.
I evaluated all of that in the context of FDA regulations as well as global industry standards and my experience and knowledge, based on the level 4 experience that I have as a regulatory affairs professional and product development scientist in the medical device world, and that's how I arrived at my opinions as

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regards what should have been in the labeling and was missing from the labeling.
Q. Okay. And I'm not quite sure you answered my question. Let me ask it this way: The items that you just told me about that you reviewed, you did that because plaintiff's lawyers asked you to?
A. They asked me to review the documentation and arrive at opinions.
Q. Right.
A. I told them the kinds of information that I needed to review, and I did some of my own independent research as well.
Q. Okay.
A. And then, of course, I know the standards that are applicable.
Q. Right.
A. And it was based on that that I arrived at my opinions, but I was asked to let counsel know what my opinions would be.
Q. And that whole process of this review of pelvic mesh documents, et cetera, began because plaintiff lawyers asked you for your opinions; correct?

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A. Yes. Just as it would be the -- but it would be the same type of methodology, the same type of process.
Q. I'm just asking how the process got started --
MR. GOSS: Please let her finish her answer.
THE WITNESS: In a consulting agreement with the client where I would be helping them with developing their labeling, I would undertake the same type of evaluation and say, "No, this is what we need to put in the labeling for it to meet the standard of care for the purpose of medical device labeling."
BY MS. SUTHERLAND:
Q. Okay. I think I'm going to move to strike everything after "yes" because my question really was you started this process because plaintiff lawyers asked you to. Isn't that fair?
MR. GOSS: Objection. Form.
THE WITNESS: It's a fair question, but I think it needs to be characterized that the process that I

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followed is the very same methodology and process that I follow for a pharmaceutical or medical device client where I'm assisting them with labeling.
BY MS. SUTHERLAND:
Q. And I got that. My question is: Didn't that process start, in fairness, Dr. Pence, because plaintiff lawyers asked you to?
MR. GOSS: Objection to form.
BY MS. SUTHERLAND:
Q. Isn't that true?
A. For the mesh products, that is true. That was -- that was what I was asked to review the information, let them know what my opinions would be.
Q. FDA didn't ask you for your opinions on pelvic mesh; correct?
A. No, they did not.
Q. And no mesh manufacturer asked you for your opinions on pelvic mesh; right?
A. No, they have not.
Q. All right. So the folks that have asked you for your opinions on pelvic mesh have been plaintiff lawyers?

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A. Yes. That said, the 2015 update to the labeling for TVT and TVT-O reflects much of what I -- a number of the -- a lot of the safety information that I stated in my report was missing and should have been included, and that now has been included.
MS. SUTHERLAND: Okay. I'm going to move to strike everything after "yes."
BY MS. SUTHERLAND:
Q. Are you intending to offer any specific causation opinion in the Jennifer Ramirez case?
A. No.
Q. All right. Are you intending to offer any general causation opinion in the Jennifer Ramirez case?
A. No.
Q. All right. Are you intending to offer an opinion on manufacturing defect in the Jennifer Ramirez case?
MR. GOSS: I'm sorry. Can you repeat that?
THE WITNESS: Do you want me to rephrase it?

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MR. GOSS: Yes.
BY MS. SUTHERLAND:
Q. Are you intending to offer a manufacturing defect opinion in the Jennifer Ramirez case?
MR. GOSS: Objection. Form.
THE WITNESS: If you are asking about -- and I recall a similar question a couple of weeks ago, I believe. If you're asking about the manufacturing process itself, maybe you can clarify, or are you asking about whether or not the product degrades, whether or not --
BY MS. SUTHERLAND:
Q. Yeah. It's the same thing I did two weeks ago. I'm not asking you about defects like degradation, roping, curling, et cetera, that other plaintiffs' experts have opined about.
My question to you is for the lot or batch that Mrs. Ramirez, this TVT-O came out of, do you have any opinions that you intend to offer about the manufacturing processes for that batch?
A. I intend to offer opinions, if

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asked, about the fact that that lot, that there had been complaints about that lot for mesh fraying.
Q. And what opinions, if asked, are you going to give on that particular topic?
A. That there was no testing that was ever done, that this was -- this batch, as well as other batches, were known to fray and have particle loss. There were complaints about particle loss. Some of Ethicon's own experts advised that they -- that some physicians, when they saw those particles, would stop and use another sling because they were concerned about those particles, the migration of those products potentially causing pain.
There were reports of those particles migrating into the vaginal wall and causing pain. There's documentation within Ethicon's own records that they did not recommend the use of a product and that this was -- in fact, there's deposition testimony that says this -- on behalf of Ethicon that says that the fraying was a product defect.

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Q. So, again, just getting back specific to Mrs. Ramirez's batch --
A. Yes.
Q. -- is what you're going to offer that there were reports or devices returned from her same batch?
A. There were at least two complaints about the batch from which her sling was made of fraying particle loss.
Q. Okay. Did Dr. -- who is the implanter in this case?
A. Cesar Reyes. Dr. Cesar Reyes.
Q. Okay. Did Dr. Reyes in his deposition -- did he mention anything about noticing any fraying of the TVT-O before he implanted it?
A. To the best of my recollection, he did.
MR. GOSS: I'm sorry. Can you repeat that?
MS. SUTHERLAND: Was that an objection?
MS. VERBEEK: Yes.
THE REPORTER: Can you repeat the objection?

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MS. VERBEEK: I objected to the form of the question.
THE REPORTER: Thank you.
MR. GOSS: I don't recall. Do we have an agreement that an objection for one is good for all?
MS. SUTHERLAND: I would assume that'd be fine. Instead of tag teaming me, I'd be fine with that.
MR. GOSS: There you go.
BY MS. SUTHERLAND:
Q. Do you want me to restate my question?
A. Yes. Thank you.
Q. Did you review Dr. Reyes' deposition?
A. Yes, I did.
Q. All right. Do you recall whether or not he testified about noticing any fraying of the TVT-O tape before he implanted it in Mrs. Ramirez?
A. Yes.
Q. What did he say?
A. As I sit here today, what I recall is that he did not notice any particle loss.

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Q. Okay. I'm trying to think how to phrase this one. Are you intending to offer an opinion that because there were reports received within her same batch, that Mrs. Ramirez's TVT-O must have frayed as well?

A. The potential was there. It's in -- the potential was there for fraying, roping, curling, and a degradation of the mesh structure with any type of stretching.

Q. Okay. I'm talking specifically, though, because I think your report mentioned those two other reports from the batch.

A. Yes.

Q. And my question is -- I understand all that, that the opinions on degradation, roping, curling, fraying that are generic to TVT and the Prolene. My question is a little more specific as to Mrs. Ramirez and her specific batch, and my question is: Are you intending to offer an opinion that because of these two other reports from the batch about fraying, that her, Mrs. Ramirez's TVT-O must also have frayed

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based on those two reports?

A. A couple of points to be made. We know that there were other slings in that batch, as you've just described, that did fray, although Dr. Reyes testified that he didn't see that. He was not aware, based on his testimony, that there was also a laser-cut mesh.

Ethicon did not -- never did tell doctors that had noticed this fraying about the issues with fraying and roping and curling. So whether or not Dr. Reyes actually looked for that, only Dr. Reyes can know. And as I sit here today to the best of my recollection, I don't believe there was a lot more discussion about whether or not he saw any particle loss or fraying other than that.

Whether or not he actually looked in the packaging to see if there were any particles, I don't know. I only know what he testified to. My point being that also on stretching, just the stretching that occurs with implanting it, it could have frayed. We know it was, in that particular

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batch, that already there were other complaints.

So if asked, I will testify that that certainly was a -- you know, could have happened. And not only that, but there's much documentation that says this was in -- the fraying and the particle loss was inherent in the mesh, the mechanically cut mesh, which was the whole impetus for the development of the laser-cut mesh. So it's inherent, by Ethicon's own words, in the mechanically cut mesh, and then for her particular batch, for there to have been other complaints, there certainly was a potential that on implantation, even if Dr. Reyes didn't notice fraying at the time he took it out to implant it, that it could have frayed, and there could have been particle loss, and as I mentioned, there have been complaints of particle loss -- the particles that are lost migrating into the vaginal wall causing pain and causing pain on -- dyspareunia.

Q. Let me try it this way: Are you going to say that Mrs. Ramirez's tape was

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frayed because of these other two reports?

A. I can't say it was frayed because I wasn't there.

Q. Okay.

A. But what I can say is the company knew that this was a defect in the product. The company knew that this happened often, and for this particular batch, they had specific complaints that showed it was an issue with other slings from this batch. So there was certainly a potential for fraying when it was implanted.

Q. Okay. I'm going to move to strike everything after "I can't say it was frayed."

Let me ask you -- changing gears. Let me ask you this: Obviously, you've got a number of opinions in this case.

A. Yes.

Q. Have you conducted any studies to support your opinions in this case?

MR. GOSS: Objection. Form.

THE WITNESS: Can you clarify what you mean?

BY MS. SUTHERLAND:

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Q. Sure. Other than reviewing documents and obviously applying your expertise and your experience, have you otherwise conducted any studies to substantiate any of your opinions in this case?

MR. GOSS: Objection. Form.

THE WITNESS: If you're asking if I've conducted animal studies or clinical studies, no, I've not.

BY MS. SUTHERLAND:

Q. Have you conducted any surveys of physicians to substantiate any of your opinions?

MR. GOSS: Objection. Form.

THE WITNESS: Specific to this case, no.

BY MS. SUTHERLAND:

Q. All right. Have you conducted any surveys of women at all -- I'll leave it broad like that. Have you conducted any surveys of women to substantiate your opinions in this case?

A. Can you be more specific?

Q. I'll give you an example. For

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instance -- and we'll get into it. One of your opinions, as I understand it, is that the patient brochure is misleading.

For example, have you conducted a survey of women who have read the patient brochure to get their perceptions on that patient brochure?

A. The best answer I can give you on that is no, I've not done the survey. However, Meng Chen, Dr. Meng Chen, for example, discussed patients with whom she had spoken who had complaints who said that based on what doctors were telling them and based on the literature that was available, that they were disappointed that neither doctors nor Ethicon had been able to tell them all the potential risks because they did not feel that the potential -- that the risk and the benefit were adequately explained to them, and had they understood the risk, they would have made a different decision.

And that comes from complaints of women made directly to Ethicon who did not feel that they were getting the appropriate

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information, and Ethicon, as the manufacturer, has a responsibility to provide that manufacturer -- or that information to the physicians as well as to the patient in the context of patient brochures, if they're going to use patient brochures, but the doctor can only relay to the patient what the doctor knows.

And if Ethicon doesn't follow through on its responsibility to provide the information to the doctor so that he -- he or she understands all the risks, then, as stated in my report, then the consenting process is negatively affected because a true, full informed consent can't be done because all the risks aren't known.

MS. SUTHERLAND: I'm going to move to strike everything after "no, I have not."

BY MS. SUTHERLAND:

Q. So again, my question really was only to you whether or not you have performed any kind of survey or study to gather what women's perceptions of the TVT-O patient brochure are.

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A. No. As you've asked the question, no.

Q. Okay. That wasn't so hard, was it? Have you ever worked at FDA?

A. No. Worked, obviously, with FDA and people at FDA but not as an employee at FDA.

Q. Right. Have you ever talked with the FDA about your opinions with respect to pelvic mesh?

A. No. As you know, I'm bound by confidentiality and have to sign confidentiality agreements to receive the documents. So that would be, to me, a conflict of interest.

Q. Has FDA ever approached you to get your opinions about pelvic mesh --

A. No.

Q. -- and you've had to tell them "No, I can't talk to you because of confidentiality"?

A. No.

Q. Has the FDA ever asked for your opinion about labeling of pelvic mesh products?

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A. No.
Q. Has the FDA ever asked for your opinion about instructions for use for pelvic mesh products?
A. No.
Q. Has FDA ever asked for your opinion about patient brochures of pelvic mesh products?
A. No.
Q. Has FDA ever asked for your opinion about anything regarding pelvic mesh?
A. No.
Q. Were you invited to be part of the 2011 AdCom concerning pelvic mesh?
A. No.
Q. Have you ever spoken to anybody at the FDA concerning your opinions regarding pre-market testing of pelvic mesh products?
A. No.
Q. And have you ever spoken to any manufacturer outside the context of litigation about pre-market testing for pelvic mesh products?
A. No, not for pelvic mesh products, no.

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Q. Okay. Have you done that for mesh products?
A. Yes. In the context of wound healing.
Q. Okay. And what product are we talking about?
A. It was -- I can't really say because I have confidentiality agreements with clients, but it was a product for use in wound healing.
Q. Okay. And was this the Class 2 product?
A. This was actually -- I believe this was a Class 3.
Q. All right. Have you talked with any manufacturer of a Class 2 mesh device concerning pre-market testing?
A. Of a mesh device? Not as I sit here today, I don't recall that, no.
Q. Okay. Have you ever been invited by the FDA to be on an advisory committee of any type?
A. No.
Q. I'm sure you've been asked this before so forgive me. Prior to your involvement in litigation on pelvic mesh, had you had any involvement whatsoever with any pelvic mesh device?

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A. In women's health issues, yes, but not a pelvic mesh device specifically, no.
Q. Okay. And the woman's health device that you're talking about, what was that?
A. It's women's health, a variety of health issues, both drugs and medical devices. And, again, I'm unable to disclose what products specifically because of my confidentiality agreements with the clients.
Q. So would it be correct to say that prior to your involvement in litigation, you had not had any involvement whatsoever in pelvic mesh devices?
A. That's fair to say, yes.
Q. Okay. Are you intending to offer any criticisms of FDA as part of your opinions at trial?
A. No.
Q. Outside of litigation, have you ever drafted a label for a pelvic mesh device?

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A. No.
Q. Outside of litigation, have you ever drafted a label for a mesh device?
A. Not a mesh device, per se. I was involved in testing, but I'm trying to recall back. I don't recall working on the labeling for that specific device.
Q. Okay. And you and I are on the same page. When I talk about labeling, you understand I'm talking about the instructions for use?
A. Yes. Yes.
Q. Okay. And I know that sometimes that gets a little semantical, label versus labeling versus IFU. Please let me know if you have confusion over the way I'm using a certain term in my questioning. I think we've been on the same page.
A. I think so too. To the best of my recollection, as I sit here today, I don't recall working on the aspects of the labeling because of the testing that I was doing on that device, which would have gone into the labeling but not the final labeling, as I sit here today.

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Q. Okay. Actually, let me break it down a little bit more focused. Outside of litigation, have you ever worked on the adverse events section of a mesh device?
A. Not specifically, no.
Q. Okay. And obviously outside of litigation, have you ever worked on the adverse events section of a pelvic mesh IFU?
A. No.
Q. All right. Outside of litigation, have you ever worked on the warnings and precautions section of an IFU for a mesh device?
A. No.
Q. And then even more focused, outside of litigation, have you ever worked on the warnings and precautions section of an IFU for a pelvic mesh device?
A. No.
Q. Okay. Outside of litigation, have you ever worked on a patient brochure for a mesh device?
A. Are you talking about polypropylene mesh?
Q. I'll start with that. Do you want

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me to ask it more cleanly?
A. Yes, please.
Q. Outside of the context of litigation, have you ever worked on a patient brochure for a polypropylene mesh device?
A. No.
Q. All right. Outside the context of litigation, have you ever worked on a patient brochure for some other type of mesh device?
A. On a dermal graft that was used for wound healing, I worked on not specifically the brochure but on background information, some of which would have been representative of what would have gone into a brochure.
Q. Okay. Was that, obviously, for some kind of mesh manufacturer? I'm not asking you who, but was that for a mesh manufacturer?
A. It was for a Class 3 type product for wound healing.
Q. Okay. And did that company have a team that they put together to work on the patient brochure for that product?

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A. Yes.
Q. All right. Were you on that team to work on the patient brochure?
A. Not on the patient brochure specifically, no. I worked on the clinical information that would have gone into the brochure.
Q. Okay. Would you have fed your clinical information to a member on that team --
A. Yes.
Q. -- for inclusion in the patient brochure?
A. Yes.
Q. Do you know what was included in the patient brochure?
A. As I sit here today, I don't recall specifically.
Q. All right.
A. It would have been the results of the clinical -- well -- as I say, I put together -- I actually -- you're talking specifically about patient brochure. The information, I don't recall as I sit here today, what would have gone into the patient

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brochure. I know that the information that I put together went to physicians.
Q. Okay. I had another question, and I lost it.
Outside of litigation, have you ever worked on a patient brochure for any device?
A. Oh --
MR. GOSS: Objection. Form.
THE WITNESS: I've worked on a lot -- a lot of information that's been provided to patients. The same types of information that goes into a patient brochure. I've done a lot of that especially on the pre-marketing side for patients where information sheets, all the information that's known as well as putting together the prototype labeling for the professional labeling as well as all the information that goes to patients, putting together informed consents for patients as well.
As I mentioned, the information sheets to tell the patient more about the product so that they can make an

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informed decision as to whether or not, in the case of pre-marketing, in the case of whether or not they actually want to participate in a clinical trial of a particular product.

And I've worked on -- let me just think back a minute because it's been over 40 years of experience. I certainly have worked on information that was to be presented in patient forums about particular -- particular products and --

BY MS. SUTHERLAND:

Q. I'm not sure I know what that means. What do you mean "patient forums"?

A. On different seminars for patients to learn more about a particular product, to better inform them about particular products.

Certainly put together the clinical information that would have gone in to any patient -- any patient brochures. As I've mentioned before, in the context of working within companies -- same as at Ethicon -- they have a team. And it's not any one

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particular person that actually puts a brochure together, puts the labeling together. The different expertises contribute their component, and then that's pulled together typically finally by regulatory for submission, but it's a team that puts that together. So certainly, I've sat on those teams.

Q. Okay. Well, that's part of my question. For instance, at Ethicon, we know it's a copy -- what's called a copy review team --

A. Yes.

Q. -- that decides the final approval of what goes into, for instance, a patient brochure; correct?

A. Right.

Q. Is it your testimony that you have sat on similar such copy review teams for patient brochures for implantable devices?

A. For implantable devices?

Q. Yes, ma'am.

A. For implantable devices, I have done more on the pre-clinical side where I've put together all of the patient

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information that was going to go to the patients that were going to have a device implanted.

Q. And that's what you're talking about, if I'm following you, is the consent that you do for them to participate in, like, a clinical trial?

A. It's not just the consent. It can also be in we call them information sheets.

Q. Right. But it's for participation in a clinical trial? Is that the context that you're talking about?

A. Yes. On the pre-clinical side, yes. I'm sorry. The pre-marketing side.

Q. Pre-marketing. Not pre-clinical.

A. Not pre-clinical. Pre-marketing side.

Q. So to get to my question, have you sat on a copy review team that worked on a patient brochure for an implantable device after it's been cleared or in the clearance process?

A. I may have. I don't recall specifically, as I sit here today.

Q. Okay. Have you sat on such a team

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for a patient brochure for an implantable mesh device?

A. No.

Q. All right. And I would assume, then, you have not sat on such a team for a patient brochure for a pelvic mesh device?

A. That's correct. I have not.

Q. Okay. Now, you told me that you describe yourself as a scientist; correct?

A. Yes. I am a scientist.

Q. Okay. And briefly -- I don't have your CV in front of me. I know I've read it multiple times. Tell me why you describe yourself as a scientist.

A. I work -- well, first of all, let's talk about educational background.

Q. Yeah. Let me start with that.

A. My educational background is in science. I have an undergraduate degree in microbiology with -- a major in microbiology and minors in chemistry and zoology, certainly all scientific fields. My doctorate, my Ph.D. is in toxicology with a minor in pharmacology, again, all medical sciences.

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My work has involved science, including product development science, both pre-clinical testing, whether that's in vitro or in vivo testing, as well as clinical testing, all of which involve, of course, science.

Work in manufacturing as well and ensuring that products are manufactured appropriately, according to standards. As a product manager, overseeing the start of a project from discovery all the way through to product launch and as a regulatory scientist.

Q. Do you describe yourself as a pharmacotoxicologist, or is there a particular science field that you use more frequently than others to describe yourself? Does that make sense?

A. Well, I think I understand your question. Let me give it a try.

I describe myself as a product development expert, product development scientist, as well as a regulatory expert in regulatory sciences.

Q. Okay. All right. And --

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A. Because my -- the scope of my expertise involves, as I was noting, and that's how I developed my career, from basic research all the way through to product launch and post marketing.

So my career has encompassed that entire scope of all -- when I teach, for example, I put it into different buckets, if you will, for my students to help them to understand that you have the manufacturing, the quality system component. You have the pre-clinical testing, and you have the clinical testing.

And then, of course, that all comes together in the regulatory arena in order to get a product cleared or approved, whichever the case may be, providing that the data show that it's safe and effective, and it's a quality product and that there's a favorable benefit/risk ratio, and then you have the pre-marketing and the post-marketing, which should be a continuum.

As long as the product is being marketed, there's always testing and risk analysis and feedback that has to happen,

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and it's that entire scope and that entire spectrum of product development which I have over 40 years of experience in and have directed my career to being able to understand and evaluate and guide products through that entire development process.

Q. Okay. And keeping that answer in mind, that entire development process, the spectrum that you just described to me, has any of your experience in that entire spectrum ever concerned a pelvic mesh product in your 40 years?

A. Not pelvic mesh.

Q. Okay.

A. Other than in the context of litigation.

Q. Yeah. Outside of litigation, the spectrum of experience that you just talked about on product development, that's never included a pelvic mesh product?

A. I have not, on the manufacturer's side, been involved in the development of a pelvic mesh product. However, all of that same level -- all of that scope, I should say, and that spectrum of experience and my

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experience and knowledge of all of those areas, I applied in the context of evaluating all of the information, the deposition testimony, internal documents, standards, guidance, regulation, scientific medical literature, I applied all of that and integrated that knowledge together to arrive at my opinions in this case in the very same fashion that I would for advising clients or if employed by a company, that I would participate at the company as a part of the product team, I apply the same type of methodology.

Q. Okay. And my question, I guess, was just that you have not applied that methodology outside the context of litigation for a pelvic mesh product.

A. That's correct.

Q. Right. So a company has not asked you to employ your expertise for a pelvic mesh product; correct?

A. Not for a pelvic mesh product. That's correct.

Q. The only folks that have asked you to apply your expertise have been plaintiff

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lawyers; correct?
A. For pelvic mesh products, yes.
Q. Okay. Have you ever participated in any cadaver study of polypropylene mesh?
A. No.
Q. Have you ever participated in any animal study for polypropylene mesh?
A. No.
Q. Have you ever designed any clinical trials regarding polypropylene mesh?
A. I've not designed one specifically for polypropylene mesh. I've considered designs, but I've not designed one.
Q. All right. And when you considered designs, was that outside the context of litigation?
A. No. It was in the context of litigation.
Q. All right. Have you ever been involved in any clinical research concerning polypropylene mesh outside litigation?
A. No.
Q. Have you ever designed a pelvic mesh?
A. No.

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Q. Have you ever done any lab work regarding polypropylene mesh?
A. No.
Q. As I understand it, your company Symbion, does that have a lab?
A. No.
Q. All right. Do you own any lab equipment?
A. No. We work with -- when we're working with clients, and we're working in pre-clinical research where a laboratory environment is needed, we identify contract laboratories to do that work, and we help to design the testing.
We oversee and sometimes inspect the facilities to make sure that they're adequate, that can do what -- they can meet the requirements for the testing, particularly if it's good laboratory practice standards. I teach good laboratory practice that they meet GLP requirements. If it's a study, pre-clinical study that requires GLP standards be met, must be done under GLP.
Q. Are you saying GOP or GLP?

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A. Sorry. GLP. Good laboratory practices.
Q. I'm not going to talk politics with you.
A. Sorry. So we could be here all day; right? We're teasing.
So I teach GLP, and I've done inspections of facilities to be sure that they meet the requirements for a GLP testing facility and then help to design the studies, oversee them, review the study reports, go back and forth with the contract laboratory with questions to ensure that we get the final report that is accurate and represents what actually was done in the study.
Q. Okay. I'm going to respectfully move to strike everything after "no" because I think my question was does Symbion own any lab equipment?
A. No.
Q. All right. Have you ever done any biomechanical testing of polypropylene mesh?
A. No.
Q. Ever done any testing of a mesh

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explant?
A. No.
Q. Have you ever looked at a mesh explant under a microscope?
A. I've looked at photos but not under a microscope myself.
Q. Okay. And the photos that you're talking about, would that have been in medical literature that you looked at?
A. Medical literature or in the context of a trial.
Q. Like a photo that one of the experts took --
A. That's correct.
Q. -- of a mesh explant. Okay.
Have you -- first of all, you know what a DDSA is; correct?
A. Yes.
Q. And what is it? A device design safety analysis.
A. Yes.
Q. All right. Have you ever done a DDSA for a mesh product?
A. There are different terms that are used, DFMEA, that kind of thing, I've been

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involved in those, yes, for mesh -- not mesh. For other devices.
Q. Let me get a -- and I'm going to ask you about DFMEA right after this one. Let me get a clean question and answer.
Have you ever been involved in performing a device design safety analysis for a mesh product?
A. No.
Q. Have you ever reviewed a device design safety analysis for a mesh product outside the context of litigation?
A. No.
Q. Okay. Now I'll do the DFMEA.
A. Okay.
Q. Am I correct, Doctor, that an FMEA is a failure mode evaluation analysis?
A. Failure mode effects analysis.
Q. And have you ever performed an DFMEA for a mesh product?
MR. GOSS: Objection to form.
THE WITNESS: Not a mesh product, no.
///
BY MS. SUTHERLAND:

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Q. All right. Have you ever reviewed an DFMEA for a mesh product outside the context of litigation?
A. Not outside of the context of litigation.
Q. All right. Do you consider yourself an expert on how mesh performs in vivo?
A. Can you clarify what you mean?
Q. Have you ever yourself studied how mesh reacts in vivo clinically?
A. Have I done the clinical testing myself?
Q. Right.
A. No. In fact, I've opined that the clinical testing has been inadequate that manufacturers have done.
Q. Okay. I'm going to move to strike everything after "no."
Have you ever been involved in a clinical trial -- let me strike that.
You understand when I talk about a clinical trial, that I'm talking about actual humans being involved; right?
A. Yes. I teach clinical trials at

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college.
Q. I know you do. I'm doing it for the jury and for myself.
Have you ever been involved in a clinical trial to evaluate the safety or efficacy of a medical device where part of that device was polypropylene mesh?
A. Not polypropylene, no.
Q. All right. Have you been involved in a clinical trial to evaluate the safety or efficacy of a medical device where part of that device was something other -- a mesh other than polypropylene mesh?
A. Yes.
Q. And is that the Allograft that you talked about?
A. It was in -- it actually was a different product, but it was a part of the product that was being evaluated prior to the final product.
Q. Okay. Like a prototype?
A. Yes.
Q. Okay. What size clinical trial was that?
A. I don't recall, as I sit here

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today, the actual numbers of patients.
Q. Do you know if it was a hundred?
A. If I recall correctly, it probably was more than that, as I sit here today without checking back.
Q. Okay. Well, when was it?
A. That particular trial was, to the best of my recollection as I sit here today, mid to latter 1990s.
Q. Okay. Have you ever done any kind of mechanical testing on the TVT-O?
A. No.
Q. Have you ever done any kind of testing or measurements on the Prolene mesh?
A. No.
Q. I had asked you before about whether or not you have looked at the new drug application for Prolene sutures.
A. Yes.
Q. Have you now reviewed the entire NDA for Prolene sutures?
A. No. I think I've testified before I was not able to. I don't have a copy of that to review.
Q. Okay. And I think I had asked you

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before if you had asked for that from counsel, and I thought you told me you had.
A. To the best of my recollection, I had, and it wasn't -- it wasn't available.
Q. Provided?
A. Yeah.
Q. Okay. All right. Obviously, you've never diagnosed stress urinary incontinence.
A. No.
Q. Have you ever treated stress urinary incontinence?
A. No.
Q. Have you ever made a recommendation to a woman on the options available to her to treat stress urinary incontinence?
A. I have talked with women who -- about the options that are available.
Q. And would this have been, like, friends -- I don't want names or anything.
A. Yes. Yes.
Q. About how many women have you talked to about the options available to treat stress urinary incontinence?
A. Oh, it would be probably in the

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order of maybe five.
Q. All right. And do you recall what options you talked with them about?
A. Just told them about pessaries, told them about bulking agents, told them about Burch colposuspension, certainly the topic of pelvic mesh -- well, the mesh came up. Clearly, I don't recommend that based on everything that I've reviewed over the last few years. So when they ask, I give them my opinion.
Q. Have you recommended a Burch to a woman?
A. No. I would never make a recommendation. And, you know, and I don't discuss with people that -- I don't volunteer that I'm working in litigation. I'm very discreet about what I say, but if anybody asks me because they know I'm in -- they know I'm a scientist, and clearly, you know, there are some people, obviously, who know that I've been at trial, that information is available.
When I'm asked, you know, I talk to them about the various options, but I would

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never make a recommendation. That's something that -- I'm not a clinician. They need to be evaluated appropriately.
Q. By a doctor?
A. By a doctor.
Q. Medical doctor?
A. By a medical doctor. And based on their own particular situation, what their issues are, discuss with the doctor what the options are. It's just that if someone asks me, you know, "Do you know what's available? What do you think about this?" As a scientist, an educated scientist in this area, I can give them my thoughts.
But I would never make -- I would never tell them what to do. That's a decision -- and that goes to the consenting process that we were talking about earlier. They need to know all the information about the products to make an appropriate decision for themself.
Q. For the women where you have just talked about the options for treatment of stress urinary incontinence, have you talked with them about the risks that you're aware

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of with the Burch procedure?
A. We really haven't gotten to that level of detail with them. It's very cursory conversations.
Q. Okay. Have you ever been in the operating room when a TVT-O was actually implanted?
A. I've seen videos, but I've not been in the operating room, yeah.
Q. Was it an Ethicon training video on TVT-O that you've -- are referencing there?
A. Yes. As well -- yes. And I've looked at other videos of slings as well. And there are even some that you can -- where certain doctors have posted various --
Q. Their own surgeries?
A. Their own, and I've looked at those as well.
Q. Have you watched a Burch surgery?
A. To the best of my recollection as I sit here today, I have looked at a video of that.
Q. All right. Do you recall when you did that?
A. I don't. Sometime within the last

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couple of years --
Q. Was that --
A. -- but I don't recall specifically.
Q. I'm sorry. Was that just a video that you found off of, like, YouTube --
A. Yes.
Q. -- or was that a professional education video?
A. To the best of my recollection, it was something that I found on YouTube.
Q. All right.
A. And, of course, there are lots of pictures, and even in the training materials, you know, for Ethicon and other places, there are pictures of procedures, and it discusses those procedures. So I've certainly reviewed those. Textbooks.
Q. All right. Let me ask you this: See what I get.
A. You're going fishing?
Q. I'm going fishing.
Would you agree that there are patients who have had a TVT-O implanted who have had no complications?
A. I can't answer that as asked yes or

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no because I don't know every patient that has been implanted and whether or not what complications they may or may not have had as well.
It's also in the literature and documented that patients may have -- particularly women who are not sexually active may have erosions that they're not aware of, and without an actual pelvic examination, physical examination, that that can't be -- that may not be detected. So for several reasons, I'm unable to say yes or no the way your question was asked.
Q. Okay. Let me ask a couple of follow-ups. It's correct, then, that a woman can have an erosion and be completely asymptomatic; correct?
A. In the situation that I described where she isn't sexually active, and it's -- it's small, it may not be bothering her, is my understanding as I sit here today. It doesn't mean that it may not bother her long term, and that also is an important point because what we're seeing in the literature is that just because a patient hasn't had a

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complication that has affected them a year or even two years out, these are permanent implants, and it's well known and, in fact, Ethicon's own employees have testified that, for example, erosions are a lifelong risk as long as the implant is there.
And as I started to mention, in the literature, it's showing that a number of complications actually increase in a percentage of patients who are experiencing -- experience them over time, which all the more supports why one needs to study a permanent implant long term to see what the complications may be.
And also because there is a chronic foreign body reaction that is set up and depending on what the mesh -- the biomaterial may be, et cetera, and the characteristics of the particular implant may be, that long-term inflammation may also ultimately cause complications.
So my point being that just because a woman hasn't experienced a complaint that has bothered her in a year doesn't mean that five years from now she isn't going to have

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one. The data supports that the data -- the medium to long-term data on these products is still, at this point in time, very limited.
Q. Okay. I'm going to move to strike everything after you finished your first sentence, and I've forgotten what that was.
Let me ask it this way: Do you intend to offer an opinion that every woman implanted with a TVT-O will have a complication from that mesh?
MR. GOSS: Objection to form.
THE WITNESS: I can't say they will. What I can say is that there is a potential for complication. So they may not. They may not.
BY MS. SUTHERLAND:
Q. All right. You mentioned before the need for long-term clinical data for permanent implants.
A. Yes.
Q. And I know I've asked you this before, and I don't think you gave me a specific time frame a couple of weeks ago when I asked this. Do you have a specific

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time frame in mind today that, in your opinion, constitutes what you call long-term for a permanent implant?
MR. GOSS: Objection to form.
THE WITNESS: In the literature --
BY MS. SUTHERLAND:
Q. Let me ask a better question because that was so convoluted I lost it.
A. Okay.
Q. As I understand your opinion, it's that for a permanent implant such as the TVT-O, a manufacturer needs long-term data; is that right?
A. Yes. Yes.
Q. All right. Now, do you have a specific time frame that you're ascribing to "long-term data"?
A. A medium term is three to five years. Long-term would be ten years.
Q. Okay. And is it your opinion that --
A. Or longer than five years but at least ten years would be helpful.
Q. All right.

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A. And that is also described in some pieces of literature.
Q. So is it five years, or is it ten years?
A. Three to five for mid, for medium. Ten years would be long-term for a permanent implant.
Q. Okay. And so for a permanent implant like the TVT-O, are you going to offer an opinion at trial that Ethicon should have had ten years worth of data before they marketed the TVT-O?
A. No, because that becomes -- that -- there's a practicality aspect, obviously, as well. What they should have done, however, is to continue a registry and have follow-on data so that they're collecting that data. But before you even get to that point, there is a lot of testing that should have been done pre-marketing that they didn't do that they should have understood before these products were implanted in women.
Q. And I'm going to get to that because that's one of your opinions in your report. I do promise I am going to get to your opinions.
Would you agree that there are women where the TVT-O has been placed where it's been effective to treat their stress urinary incontinence?
MR. GOSS: Objection. Form.
THE WITNESS: Based on my understanding, that's correct.
BY MS. SUTHERLAND:
Q. All right. Would you agree that there are a lot of doctors in the United States who believe that the TVT-O is safe and effective?
MR. GOSS: Objection. Form.
THE WITNESS: Based on my knowledge of the situation today, there are doctors who, yes, believe it is safe and effective. There are others who are changing their opinions.
BY MS. SUTHERLAND:
Q. Okay. Other than the Burch procedure, are there other surgical procedures that you're aware of for the treatment of stress urinary incontinence without the use of mesh?

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A. Yes.
Q. Okay. And what are they?
A. Well, the Burch can be done open or laparoscopically. There's the MMK, the Marshall-Marchetti-Krantz. Paravaginal repairs, different types of suspensions and, of course, then there are -- you said surgical, though; right?
Q. Yes, ma'am.
A. So excluding bulking agents.
Q. Yeah. When you talk about suspensions, are you talking about the use of an autologous sling as well?
A. Yes, definitely an autologous sling or an Allograft as well.
Q. Yeah. By "Allograft," do you mean either cadaver or some kind of animal?
A. Well, that would be a xenograft, but yeah. So cadaver tissue, yes. There are different options as well as the autologous grafts.
Q. All right. Now, are you familiar --
A. Autologous sling, I should say.
Q. I'm sorry.

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A. I'm sorry.
Q. I don't mean to cut you off.
Are you familiar with the risks associated with those different procedures that you just mentioned?
A. I think so, yes.
Q. All right. So with respect to the Burch open procedure, can you tell me what are the risks associated with that procedure?
A. Well, certainly you have --
MR. GOSS: Objection. Form.
THE WITNESS: -- the same risk of anesthesia that you do with any surgical procedure. There's the risk of pain, pelvic pain, the risk of dyspareunia, the risk of bleeding, the risk of organ perforation, the risk of voiding dysfunction. Those are some of the representative ones.
BY MS. SUTHERLAND:
Q. And I had asked that specific to Burch, but would those same risks be applicable, for instance, to the Burch performed laparoscopically?

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A. Yes.
Q. And would those same risks be applicable to the MMK?
A. That's my understanding. That's correct.
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. Okay. Do you know how many doctors perform the MMK today?
A. I don't know how many doctors. It's my understanding that it's not performed very often today.
Q. Okay. Do you know if it's even taught in medical school anymore?
MR. GOSS: Objection. Form.
THE WITNESS: I can't say for every medical school whether or not it's taught or not. I haven't done that evaluation.
BY MS. SUTHERLAND:
Q. All right. Would those same risks that you mentioned be applicable to an autologous sling?
A. Yes. I think what we're talking about, if you're going -- if you're talking

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about a foreign body, there are -- there are differences where there's -- where there's a graft being placed. Even with a biological graft, you can get erosion that you obviously don't have in the Burch colposuspension.
Q. And did you say can you have a foreign body reaction when you use a foreign body other than a mesh?
A. Well, I'm speaking more there about the polypropylene meshes.
Q. Okay. I'm excluding the meshes for right now.
A. Okay.
Q. I'm just wanting to get your understanding of the risks that are attendant to, for instance, that you said an autologous sling for the treatment of SUI.
MR. GOSS: Objection. Form.
THE WITNESS: That's one's own tissue.
BY MS. SUTHERLAND:
Q. Right. Can your own tissue erode?
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:

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Q. Or do you know?
MR. GOSS: Objection. Form.
THE WITNESS: I haven't actually studied that. I suspect that it could, but I haven't actually studied that.
BY MS. SUTHERLAND:
Q. Can the sutures that are utilized in these other surgical procedures for the treatment of SUI erode?
A. Yes.
Q. And can you have a reaction to the use of cadaver tissue?
MR. GOSS: Objection. Form.
THE WITNESS: You could, yes.
BY MS. SUTHERLAND:
Q. I mean, that's a risk associated with surgical treatment of SUI where you use cadaver tissue, isn't it?
MR. GOSS: Objection. Form.
THE WITNESS: It's a potential risk.
BY MS. SUTHERLAND:
Q. All right. Now, have you -- strike that.

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What, if anything, have you done to determine whether doctors knew of these risks for surgical treatment of SUI other than with mesh?
MR. GOSS: Objection. Form.
THE WITNESS: If I understand your question correctly, review of the literature, review of textbooks about the procedure, review of deposition testimony. I think that's probably a good summation.
BY MS. SUTHERLAND:
Q. Okay. Have you done any kind of survey of physicians to understand their state of knowledge with respect to the risks you've listed for surgical options for the treatment of SUI other than with mesh?
MR. GOSS: Objection. Form.
THE WITNESS: I've not done a survey, no.
BY MS. SUTHERLAND:
Q. All right. So if I'm understanding you correctly -- let me ask you this: Would it be fair to say that you are aware of these risks because of your review of the

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medical literature?
A. Yes.
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. All right. Is it your opinion that doctors are aware of these risks if they have reviewed the medical literature?
MR. GOSS: Objection. Form.
THE WITNESS: Yes. And they were also taught.
BY MS. SUTHERLAND:
Q. In medical school?
A. In medical school or more specifically in their fellowships or -- internships and fellowships, residencies.
Q. Now. Is it your opinion that a manufacturer of a mesh device for the surgical treatment of stress urinary incontinence has a duty to warn of risks associated with the use of the device?
A. Yes.
Q. All right. Now, in your definition of risks associated with the use of the device, are you including risks that also are associated with general surgical

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treatment of SUI that does not use mesh?
MR. GOSS: Objection. Form.
THE WITNESS: Yes. And more specifically, the labeling should include information about frequency, severity, chronicity of those particular risks.
BY MS. SUTHERLAND:
Q. Okay. And I'm going to get to that. So I'm going to move to strike everything after "yes" for right now.
Well, I'll go ask you this while we're on that. Is there any IFU that you've seen for a pelvic mesh device that includes rates of frequency for their adverse events?
MR. GOSS: Objection. Form.
THE WITNESS: Not for a pelvic mesh device of the ones that I have reviewed that we discussed earlier.
BY MS. SUTHERLAND:
Q. Of the ones you've reviewed, yeah.
What about any mesh device? Does any mesh device that you've reviewed, does the IFU include frequency rates for their adverse events?

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MR. GOSS: Objection. Form.
THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs include clinical data that shows the frequency of particular adverse events in the clinical testing.
BY MS. SUTHERLAND:
Q. Okay. And would that be a separate section under clinical performance in that IFU?
A. To the best of my recollection, yes, it's included there. But it's present in the IFU.
Q. And, now, I'm assuming your opinion -- well, let me just ask you: Is your opinion that in the IFU Ethicon, under the adverse events section where it listed adverse events, it should have listed frequency rates for those adverse events?
A. They should have -- let me go back to the purpose of labeling, which is to provide the information to the physician that he can also discuss with the patient to make an informed decision. Like Dr. Reyes

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said, you know, he wanted -- if I recall correctly, he wanted to make an informed decision, and information to make an informed decision includes, because just as you've mentioned there, some of the same types of side effects, risks that occur with the mesh products can occur with other types of surgery as well.

So in order to make an informed decision about what is the appropriate alternative for this woman, like in the case of Ms. Ramirez, her case, a 28 years old, whether or not you implant a mesh product or use something else, understanding the frequency, the severity, the permanency, chronicity of these in contrast to other procedures where there may be -- there's a possibility or the potential for adverse effects but that don't have the same level of severity, or they don't occur as often, and they don't last as -- they don't last chronically for the lifetime of the patient.

And then, of course, you have the specific mesh-related complications as well. But yes, and if you look at the G91-1, the

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Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be included as well.

MS. SUTHERLAND: All right. Would you read my question back.

(Record read by the reporter as follows:

Is it your opinion that in the IFU Ethicon under the adverse events section where it listed adverse events it should have listed frequency rates for those adverse events?")

BY MS. SUTHERLAND:

Q. And I'm -- if I missed your answer, I apologize, but I do want an answer to that question if I could get it.

A. Yes, that's my opinion.

Q. Okay. Now --

MR. GOSS: You missed that in the last answer?

MS. SUTHERLAND: I missed that one. You saw how long she had to scroll for it. Come on.

Guys, we're at 12:15. When do

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you guys want to break for lunch?

MR. GOSS: How about now? Whenever you're at a stopping point.

MS. SUTHERLAND: I mean, I think I'm at a -- good enough now as later.

MR. GOSS: All right.

THE VIDEOGRAPHER: All right. With the approval of counsel, going off the record. The time is approximately 12:15 p.m.

(Lunch recess taken from 12:15 p.m. to 1:01 p.m.)

THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 1:01 p.m.

BY MS. SUTHERLAND:

Q. Dr. Pence, welcome back from lunch.

A. Thank you.

Q. I wanted to follow up on what we had kind of been talking about before the break, which was your opinion that there needs to be frequency rates set out beside adverse events in the IFU.

A. Yes.

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Q. All right. And if I understood you correctly, you were relying on the Blue Book Memo for that opinion?

A. Yes.

Q. All right. And I -- where did it just go? Oh.

A. As well as experience.

Q. Okay. And in case I didn't ask this before, is there any pelvic mesh IFU that you have reviewed that lists frequency rates outside adverse events?

A. No.

Q. Okay. Now, in looking at the Blue Book Memo, which I marked as Exhibit Number 2 --

A. I might also add that in addition to the Blue Book Memo, there's also the GHTF labeling document, which talks about all residual risk, and we may have talked about in the prior deposition that risk is a combination of the probability of occurrence and severity.

Q. Well, the probability of occurrence and severity is the definition of how you define a risk in the GHTF document; correct?

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A. That's the definition of risk, yes. It's a combination of those.
Q. Now, the GHTF labeling guidance does not set out anything about listing frequency next to adverse events, does it?
MR. GOSS: Objection. Form.
THE WITNESS: It talks about -- let me just refresh my recollection --
MS. SUTHERLAND: Okay.
THE WITNESS: -- but it says that all residual risk, and risk by definition includes a combination of probability of occurrence and severity. And some of these documents, you know, various pieces of literature also discuss, in addition to the guidances, discuss severity as being important.
BY MS. SUTHERLAND:
Q. And when you get to the document, tell me what you're looking at, please.
A. Okay. This is the label instructions for use in medical devices.
Q. Okay.
A. GHTF guidance.
Q. Right.

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A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling."
MR. GOSS: Let the record reflect that the witness is reading from page --
THE WITNESS: Unfortunately, it doesn't have a page number.
MR. GOSS: Or section number.
THE WITNESS: Section number 5.0, General Principles, on the beginning or two pages after that at the top of the page, there's a bullet point.
MS. SUTHERLAND: All right.
MR. GOSS: Have you marked this as an exhibit?
MS. SUTHERLAND: Yeah. We can. I mean, we did last -- two weeks ago I marked all of the --
MR. GOSS: I was just going to reference it as what exhibit number it was. I didn't know if you'd marked it yet.

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MS. SUTHERLAND: No, I haven't. Certainly you're welcome to if you want to as Exhibit 9.
If you don't mind sticking that on there. That means you've got to give it up.
(Exhibit Number 9 was marked for identification.)
MR. GOSS: That's how you lost your last one; right?
THE WITNESS: Yes. Exactly.
MS. SUTHERLAND: This was his idea.
BY MS. SUTHERLAND:
Q. So if I'm right, are you relying on the GHTF labeling guidance and the Blue Book Memo for your opinion that frequency rates need to be listed out beside adverse events in a pelvic mesh IFU?
A. Yes. As well as I mentioned my own experience and also the fact that, if I'm recalling correctly as I sit here today, that Ethicon's corporate designee testified, regulatory corporate designee Susan Lin, testified, again as I recall, if I recall

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correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard.
Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1 standard; correct?
A. Right.
Q. And if you'll turn to the adverse event section in there, and I pulled down the page, down at the bottom, do you see where --
A. Yes.
Q. And I don't have a copy. So I'm kind of going by my notes.
MR. GOSS: What do you need? Blue Book?
MS. SUTHERLAND: Blue Book Memo.
MR. GOSS: It may have my writing on it, but if it does --
MS. SUTHERLAND: I won't look at your super secret notes unless they're very helpful.
MR. GOSS: Yeah.
BY MS. SUTHERLAND:
Q. And if I am with you at the right

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language, you're looking under adverse reactions under Section 8 of the Blue Book Memo?
A. Yes.
Q. And you're looking under the third paragraph that begins "Adverse reactions should be listed"?
A. Yes.
Q. All right. Is this what you're -- the standard that you're relying on when you opine that "Adverse reactions should be listed in descending order according to their clinical significance as determined by their severity and frequency"?
A. Correct.
Q. All right. And let me ask you -- I'm going to had you the TVT-O IFU that I'm going to mark as Exhibit Number 10.
(Exhibit Number 10 was marked for identification.)
BY MS. SUTHERLAND:
Q. And I have marked on mine --
MR. GOSS: Don't worry about it. What is that?
MS. SUTHERLAND: It's just the

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IFU.
BY MS. SUTHERLAND:
Q. And I want you to turn with me, Doctor, to the adverse reaction section.
A. Is this the IFU that was in use with Ms. Ramirez?
Q. I pulled it from Dr. Reyes' deposition; so I can represent to you that I assume so.
A. Okay.
MR. GOSS: Let the record reflect that on the first page, it says 2005. You might ask her if 2005 would also be the same as the 2010.
BY MS. SUTHERLAND:
Q. Would that be the same as the 2010?
A. The adverse reactions during this period. Even if it were a different --
Q. Yeah. The adverse reactions would be the same?
A. The adverse reactions would stay the same for this time period.
Q. Yeah. Yeah. So turn with me to the adverse reaction section of the IFU.
A. Yes.

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Q. And now I understand and I'm going to get to your opinion about listing additional adverse reactions. Right now my question to you is: The adverse reactions that are listed there, is it your opinion that they are not listed in descending order according to their clinical significance? Actually, strike that. Let me ask a different question to begin with, and then I'll come back to that.
MR. GOSS: As long as I haven't marked on that Blue Book, you can mark that as an exhibit if you want.
MS. SUTHERLAND: Well, I marked hers as the Blue Book.
MR. GOSS: Okay.
MS. SUTHERLAND: Yeah.
BY MS. SUTHERLAND:
Q. You're not a medical doctor; correct?
A. That's correct.
Q. And you don't implant mesh obviously; correct?
A. Correct.
Q. And you don't treat complications

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associated with the use of mesh; correct?
A. That's correct.
Q. Or with surgical procedures to treat stress urinary incontinence; correct?
A. That's correct.
Q. So do you consider yourself qualified to opine as to the clinical significance of different adverse reactions associated with mesh?
MR. GOSS: Objection. Form --
(Simultaneous discussion interrupted by the reporter.)
THE WITNESS: As to the adverse events that should go into labeling, yes.
BY MS. SUTHERLAND:
Q. Okay. But are you qualified, in your opinion, to offer an opinion as to the clinical significance between different adverse events?
MR. GOSS: Objection. Form.
THE WITNESS: The way you've asked that question, I can't really give you a yes or no. So let me see if I can explain it. The clinical significance

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is determined, like within the project team, with -- based on a clinical evaluation which includes commercial experience. It includes what's in the clinical literature and clinical investigations.

And as a part of my career in product development, yes, I have often evaluated adverse reactions as regards to clinical significance and working with investigators to make that determination.

But I've done evaluations of adverse reactions for clinical significance myself, but we incorporate physicians as a part of that product team.

But the labeling here, if you read what this says, it says, "Provide frequency data from adequate clinical studies." So it's from the clinical evaluation, which I've participated in many times, that you -- based on the different types of clinical data, you determine what's clinically significant.

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Does that help?

BY MS. SUTHERLAND:

Q. Not really. Right now my question is just on are you -- do you consider yourself qualified as a non-physician to offer an opinion as to the clinical significance of the different adverse reactions that are set out in the TVT-O IFU?

MR. GOSS: Objection. Form.

THE WITNESS: I think there are two parts -- two answers -- two parts of the answer to that question, I should say.

If you're talking about in terms of determining in an event that occurs to a patient whether or not that particular event is clinically significant, in that case, I would work with the doctor to make that determination, which I've done many times.

If you're talking about clinical significance as to what goes in the labeling, that is based on an evaluation of, as I mentioned, what's

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known through commercial experience, the scientific literature, clinical investigations that are done.

And when you look at the potential -- whether the -- where there's a reasonable association of the device with the occurrence of the event, there doesn't have to be causation proved. Based on that analysis, you determine what should go in the labeling, which I did for my opinions, and yes, I am qualified to do that.

BY MS. SUTHERLAND:

Q. Okay. And my question is not asking you if you're qualified to opine as to what ought to be in the labeling. My question is: Are you qualified as a non-physician to tell me of the adverse events that are in the labeling, which are more clinically significant than others as far as the order that they ought to be listed?

MR. GOSS: Objection. Form, asked and answered.

THE WITNESS: With severity and

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frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important than another, then for that, a physician would be the appropriate person. But in terms of severity and frequency on clinical significance, yes.

BY MS. SUTHERLAND:

Q. Is that just because of your review of the medical literature?

A. No. It's review of what's in the clinical literature -- I mean, the clinical studies that have been published as well as the literature and commercial experience, what's known within the company, the input -- there's lots of documentation within Ethicon that -- where they've had meetings of their preceptors and meetings of their experts who they consult with who have discussed the importance of a number of unmet medical needs, for example, with mesh and what is important from a clinical standpoint.

Q. So if -- I'm not going to -- we may

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agree to disagree on your qualifications on that, but assuming you are allowed to opine as to the clinical significance of adverse reactions, in looking at the TVT-O IFU, are those adverse reactions listed appropriately in descending order according to their clinical significance as determined by their severity and frequency?

MR. GOSS: Objection. Form.

THE WITNESS: There are no severities and frequencies listed here to denote that aspect of whether or not they're listed in order of clinical significance.

As well, some of them are wrong, like transitory foreign body reaction may occur. It may be chronic.

BY MS. SUTHERLAND:

Q. Do you have an opinion that you intend to give that the adverse reactions that are listed in the TVT-O IFU are incorrectly listed as far as being put in descending order according to their clinical significance as determined by their severity and frequency?

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MR. GOSS: Objection. Form.

THE WITNESS: As regards to the question as you've asked it and as I understand it, that's not my intention to opine about that specifically.

BY MS. SUTHERLAND:

Q. Okay. Then let me take you to the next sentence on the Blue Book Memo, and it talks about "Provide frequency data from adequately reported clinical studies when the data is not well known to the device user and/or when needed in deciding between the use of the device and an alternative procedure or approach."

Are you with me?

A. Yes.

Q. All right. I want to break those into two questions, if I could, first.

As I understand what the Blue Book Memo says, it says you provide frequency data from adequately reported clinical studies when the data is not well known to the device user. All right? Are you with me?

A. Yes. Yes.

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Q. Do you with that?

A. Yes.

Q. All right. The device user for a pelvic mesh product is someone who's been trained in the surgical treatment of stress urinary incontinence; correct?

A. In the treatment of stress -- well, we hope so, yes.

Q. Well, the information -- I mean, the IFU, in fact, sets out that that's who ought to be using the TVT-O; correct?

A. Yes.

Q. Someone who's been trained in the surgical treatment of stress urinary incontinence?

A. That is correct.

Q. And, in fact, someone who's been trained in the use of the TVT-O; right? I mean, that's what the IFU says, isn't it?

A. Let me look at the specific language.

Q. Okay. It's actually on page 2 under "Important."

A. Yes, it does. This one does say and specifically in implanting the Gynecare

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TVT obturator device. That said --

Q. Well, now, you've answered my question. So my next question is --

MR. GOSS: Let me see that.

BY MS. SUTHERLAND:

Q. Have you conducted a study of surgeons who are trained in the surgical use -- strike that.

Have you conducted a survey of physicians who have been trained in the surgical treatment of SUI and trained in the use of TVT-O to determine whether or not they were unaware of frequency data of any adverse event?

MR. GOSS: Objection. Form.

MS. VERBEEK: Same objection.

THE WITNESS: I have not conducted a survey, but I've certainly reviewed deposition testimony where there's information about adverse reactions or potential adverse reactions that doctors were not aware of.

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BY MS. SUTHERLAND:

Q. And how many depositions of

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surgeons trained in the surgical treatment of SUI and TVT-O have you reviewed?
MR. GOSS: Objection. Form.
THE WITNESS: I don't have a specific number that I recall as I sit here today.
BY MS. SUTHERLAND:
Q. I mean, it's less than five. Wouldn't that be fair?
A. It may be more than five.
Q. Of surgeons trained for TVT-O?
A. It may be more than five.
Q. Is it going to be more than ten?
MR. GOSS: Objection. Form.
THE WITNESS: Probably not.
BY MS. SUTHERLAND:
Q. And do you know how many surgeons in the United States are trained in the surgical treatment of stress urinary incontinence?
MR. GOSS: Objection. Form.
MS. VERBEEK: Same objection.
THE WITNESS: I can tell you approximately how many urogynecologists, gynecologists, and urologists there are

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in total. How many have actually, you know, practiced in the treatment of SUI, I don't have a specific number, but there are in the high 30 thousands, if I recall correctly, of ones who are listed as active.
BY MS. SUTHERLAND:
Q. All right.
A. And practice.
Q. And if I'm understanding the basis of your opinion that frequency data from adequately reported clinical studies is not well known to the user of the TVT-O, that basis is your review of approximately ten or less depositions?
MR. GOSS: Objection. Form.
THE WITNESS: I'm saying that there -- I'll take the counter argument, so to speak, to your question that you're asking how many surgeons there are that may practice in SUI.
First of all, the labeling is the cornerstone of risk management, and the purpose is to provide all information necessary for safe and

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effective use of the product, and if you don't include information from clinical studies for very adverse events that are of high clinical significance in the labeling, then you are assuming that those 30 some-odd thousand physicians who could potentially use the product have all read all the literature that expresses that important information.
And you're also assuming, then, that all of those 30 some-odd thousand doctors have gone to specific training for TVT-O, and the TVT-O training is a cadaver lab sometimes with a proctor later as well working with a proctor.
But there's no credentialing required for someone to be able to implant a TVT-O; so they may or may not have had specific training.
But you have to go back to the point of the labeling. The manufacturer owns that document. It is the key point of communication, the IFU, with the physician who's going to be using the product. And, therefore, all necessary

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important information must be in there.
For example, the groin and thigh pain. The percentage is as high as in the 20 percents, 20 percent or more for groin and thigh pain in some clinical studies. Doctors who are implanting the TVT-O, if they've not read the literature, they're not up to date on the literature, would not know that.
That's the reason that type of information should be in the IFU.
MS. SUTHERLAND: All right. I'm going to move to strike that entire answer.
Would you read my question back?
(Record read by the reporter as follows:
BY MS. SUTHERLAND:
Q. Is that true?
A. Not as you've asked the question. No, that's not true.
Q. Are you assuming that the 30,000 or so surgeons, and it might be less, that are

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actually trained in the surgical treatment of stress urinary incontinence do not know frequency data of adverse events?
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. Are you making that assumption?
A. I'm not making an assumption. I'm stating that it's really irrelevant as to what goes in the labeling. There are standards. There are regulations, and there's a global standard for what's supposed to go into the labeling.
And going to the second point here, information when needed and deciding between the use of the device and an alternative procedure or approach, having that information is critical to understanding what the risks are for one product versus another, and without that information, the labeling does not serve its purpose which is to provide, again, all the information necessary for safe and effective use of the product.
Q. And I appreciate that, but my question is the Blue Book that you're

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relying on for your opinion that frequency data needs to be in the IFU says, "You provide frequency data when that data is not well known to the device user." And I'm trying to get what have you done to determine that the frequency data is not well known to the device users of TVT-O?
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. And you haven't done a survey of physicians; correct?
A. No. Nor did the company.
Q. You've read approximately ten depositions of surgeons for the TVT-O; correct?
A. Yes.
Q. All right. What have you done otherwise, if anything, to be able to opine that frequency data from adequately reported clinical studies is not well known to the TVT-O device user?
A. I have looked up and evaluated the total numbers of physicians that have the potential credentials to implant this device, and one has to -- Ethicon didn't --

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I've not seen any evidence that Ethicon has ever done this survey in order to exclude incorporating that information.
Q. I'm asking what you have done.
A. I have not done a survey, but short of Ethicon, who has a responsibility for the labeling, never having done such a survey, then the information needs to be included.
One would be making a large assumption to think that every physician of those 30-plus thousand has read all of the literature that's available.
Q. Aren't you making an assumption that they haven't?
A. But that's the point. The labeling --
Q. Give me a yes or no, please. Are you making an assumption that they haven't read the literature?
MR. GOSS: No, no, no. We're not going to start interrupting her by telling her what she's going to do and what she's not going to do. You can ask your question. She can answer the question. You can object nonresponsive.

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But let's not interrupt each other.
BY MS. SUTHERLAND:
Q. Aren't you making an assumption that --
MR. GOSS: Are you finished? Were you finished with your answer?
THE WITNESS: I don't remember my point.
BY MS. SUTHERLAND:
Q. I'll start over. Aren't you making an assumption that surgeons trained in the surgical treatment of stress urinary incontinence have not read the medical literature and, therefore, are not versed in frequency data?
A. What I am saying I am not making any assumption. What I'm saying is that I'm doing -- I'm recommending -- I'm opining that one ensures that the information is available, which is what a reasonably prudent medical device manufacturer would do to ensure that the information is available because one cannot know if every surgeon who might use this product has read the literature.

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Then the manufacturer who owns the label must ensure that the necessary information for safe and effective use of the product is provided.
Q. All right. Let me ask it one more time. What, if anything, have you done to determine that surgeons trained in the surgical treatment of stress urinary incontinence do not know the frequency data from adequately reported clinical studies?
MR. GOSS: Objection. Form.
THE WITNESS: I've already indicated that I've read depositions of different physicians. I've read obviously lots of internal documentation, scientific literature, and I've evaluated, I've assessed the total number of potential physicians in this country who could be using this product.
BY MS. SUTHERLAND:
Q. Okay.
A. And based on that -- and based on what should be included in the label for safe and effective use of the product, I

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arrived at my opinions.
Q. Is there an internal Ethicon document that says that frequency data for a particular adverse event is not well known to device users?
MR. GOSS: Objection. Form.
THE WITNESS: Ask that question again, please.
BY MS. SUTHERLAND:
Q. Sure. I thought you said as part of your bases for your opinion that you're relying on internal Ethicon documents.
A. Right.
Q. So is there such a document from Ethicon that says for any adverse event that the frequency data of that adverse event is not well known to device users?
A. Well, for example, there's information on roping, and -- there's documentation in Ethicon's files, I should say, on roping and fraying and that this information and the -- that that information was not made known to doctors.
Q. Let me limit it to actually to adverse events.

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A. Well, adverse events can result from that.
Q. Well, for instance, like erosion could result from one or the other of the things that you said. But I'm asking specifically about an adverse event that you think ought to be listed in the IFU with frequency data.
Is there a particular Ethicon document that you're thinking of that supports your opinion that users of the TVT-O device didn't know about the frequency data from adequately reported clinical studies?
MR. GOSS: Objection. Form.
THE WITNESS: As you've asked the question, I can't think of a specific document that says they don't know the frequency of this, but I can think of many documents that say doctors -- that this information has not been made available to doctors.
BY MS. SUTHERLAND:
Q. Okay. I'm going to move to strike after your first sentence.

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Now, you can set aside that IFU and pull out your report from this case, the 2015, and turn to pages 78 and 79, if you would. I'll tell you where I'm going with this.
I want to get from you exactly what you intend to tell a jury ought to be listed under the adverse reactions section of the TVT-O IFU in 2010.
Does that make sense?
A. Yes, it does.
Q. All right. So I've read through your report and saw the list on page 78 and 79, and I want to ask you is this listing on these bullet points from 78 to 79 what you intend to tell a jury in this case should have been included in the adverse reactions section of the TVT-O IFU?
A. Yes, that's correct.
Q. All right. Now, are there any additional -- I want to be sure I've got the whole list for the adverse reactions section. Are there any additional adverse reactions that you think should be listed here? And I'll ask you about one because I

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don't want to play any tricks on you.
Groin pain and leg pain is not listed in those bullet points. Should it be, according to your opinion?
A. Yes. And let's see. I do address that on page 81.
Q. Yeah. And that's why --
A. And 82 and 83.
Q. -- I'm asking should those be additional -- two additional bullet points that we add to these bullet points on 78 and 79?
A. Yes. And that's indicated on page 83 where I note that "By no later than 2007, Ethicon had the responsibility to update the IFU to advise physicians that leg, groin, inner thigh pain may be chronic, may require analgesics for pain management and may require mesh excision and complete mesh removal, may not be possible. As well, leg movement may be affected and, moreover, the likelihood of this complication is significantly higher for TVT-O implantation versus TVT."
Q. So let me be sure I've got a

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complete listing here. As I understand it -- well, first of all, let me ask you. On your first bullet point on page 78, you've got there "Pain, including chronic pain," and then you've got a parenthetical with note.
Now, the parenthetical you're not saying should be included in your adverse reactions section for the IFU; correct?
A. No. My purpose, if I can explain why I included that, I wanted to be thorough so that you wouldn't look at the fact that the IFU says, "Transient pain lasting 24 to 48 hours may occur" and then say, "Well, we do say pain."
Q. Right.
A. So I'm addressing that I recognize what the IFU says, but what the IFU says is inadequate and incorrect actually.
Q. So would the parentheticals that are listed here next to these bullet points, obviously not be what you're saying should be in the TVT-O IFU?
A. I'll just check each one.
Q. Yeah.

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A. Yes.
Q. Okay. And now tell me specifically on the leg pain, groin pain issue what exactly you would add to this list language-wise?
A. "Leg, groin, inner thigh pain that may be chronic may require analgesics for pain management and may require mesh excision --
Q. Okay.
A. -- and complete mesh removal may not be possible and leg movement may be affected."
Q. So that whole --
A. And that the complication -- this goes back to what we were talking about earlier about the frequency, that the likelihood of this complication is significantly higher for TVT-O versus TVT.
Q. And so that, what all you just said, ought to be in one bullet point under adverse reactions?
A. Some of it might be in the warnings like the TVT -- this is -- the complication rate is higher for TVT-O than for TVT, for

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example.
Q. Okay. Now --
A. Because the adverse reactions are supposed to reference warnings. Those that are serious should also reference "See warnings for additional information which may also include limitations of use as a result of the potential for that adverse reaction and what might be done, if anything, to be able to mitigate that risk.
Q. Now, are there any other bullet points that we need to add to pages 78 and 79 in order for me to have a complete listing of your opinion in this case as far as adverse reactions?
A. These are ones that are missing. So obviously, you have the ones that are already in the adverse reaction listing.
Q. Right.
A. As I sit here today, I think it's -- but we do have the warnings as well.
Q. Yeah, I'm going to talk about those.
A. Okay.
Q. Now, is the listing on page 78 and

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79 in the order that you would place it according to clinical significance based on severity and frequency?
A. No.
Q. How would you order this list?
A. I haven't done that evaluation. I would do -- I would go through the process that I talked about earlier is looking at doing an evaluation of the available data through commercial experience, through what the company knew at the time of launch of the product, is documented in the documentation from the company, through the scientific medical literature, through the -- the clinical -- any clinical information that may be available for similar products if not the company's own product, looking at all of that and then evaluating what the percentages of occurrence are, what the range of occurrence is because different studies will report different ranges, look at the frequency, look at the severity, look at the permanency, the chronicity, and then as part of the project team, evaluate that and

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determine what are the most important ones, what clinicals, which ones should be presented as most clinically significant for this particular device and present them in that way.
So it's an evaluation that needs to be undertaken in that type of a framework.
Q. Okay. I'm going to move to strike everything after "I have not done that evaluation."
Would it be fair to say, though, that at least as you sit here today, you're not intending to tell a jury the order that your bullet points ought to be listed in?
A. That's correct.
Q. Okay. Now -- oh, one more thing on the bullet points. Is it your opinion, for instance, that -- let's just assume, if you will for now, that like the first three are listed in the correct order according to the Blue Book Memo. All right? Is it your opinion that they also need to have some sort of frequency rate or percentage out beside them?
A. If that data is available through

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clinical studies, which there is data available like the groin and thigh pain. There are studies that report in the 20 percents ranges for groin and thigh pain in certain studies.
Q. Okay.
A. And so for things of nature, again, yes, because that then helps a clinician, the surgeon in this case, to understand when he's deciding what type -- what the frequency of dyspareunia is, for example, and whether or not it's short term or long term.
That type of information is critical for the surgeon to know as he works with the patient to make a decision is what the best treatment is for this patient.
Q. Okay. I'm going to move to strike everything after "yes."
Actually, would you read my question back?
(Record read by the reporter as follows:
Is it your opinion, for instance, that -- let's just assume, if you will for now, that like the first three are listed in the correct order

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according to the Blue Book Memo. All right? Is it your opinion that they also need to have some sort of frequency rate or percentage out beside them?")
BY MS. SUTHERLAND:
Q. Okay. And I think your answer to that was yes; correct?
A. I think I also said that if that information is available from clinical studies.
Q. Okay. Is that information available from clinical studies for all of your bullet points on pages 78 to 79?
A. One would have to do -- there is information on all of these in the literature, yes, but that -- one would have to do an assessment of the literature and look at ranges that were reported and make determinations so that you could say, you know, ideally this information comes from the company having done its own clinical studies.
Q. Have you done the determination as to what the frequency rates ought to be for all of your bullet points?
A. I actually have in some of my

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reports some that are indicated in some of the systematic reviews that have been done. I've not done and I have looked at that in terms of looking at each one of these and evaluating the entirety of the literature and making a determination for each of these as to what I would include or whether or not it needs to be included for every one.

I have not done that determination, but it certainly, for the more clinically significant ones, that's appropriate to do.

Q. Okay. And tell me which ones are the more clinically significant ones that you're talking about there?

A. Certainly the groin and leg, inner thigh pain, the effect on walking, the erosion, the rates of erosion, the shrinkage, the urinary problems, the ones that occur most frequently.

But, again, in order to do that and give the right percentages, one would go through the process that I have already described.

Q. Okay. Now, let me turn -- well, let me make sure. Have you given me your

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opinions that you're going to offer to a jury as to what ought to be under the adverse reaction section of the TVT-O IFU?

A. Yes, in terms of missing data, yes.

Q. Right. Okay. Now, I'm going to turn to your warnings and precautions.

A. Missing adverse reactions, I should say.

Q. Yeah. So let me turn to the warnings, and am I correct that the warnings information that you think should be in the TVT-O IFU as of 2010, that is set out on pages 79 and 80 and top of 81 and also includes the leg and groin pain that you and I already talked about?

A. That's correct.

Q. All right. Is there anything else that you intend to opine ought to be in the warnings section of the TVT-O IFU as of 2010?

A. There are -- there are two points that I would add.

Q. Okay.

A. One is that factors that -- patient-related factors that may affect how

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they respond to implantation of mesh and the Ethicon documentation reflects that there are certain factors related to individual patients' medical status that might impact how well they would respond to implantation of the device or whether or not it might increase their risk for complications, in other words. So those factors would be appropriately included in the warnings and precautions section.

And then the other one is that while the -- with regard to degradation and that the mesh may degrade and that with degradation, that that may impact the safety and effectiveness, whereas I -- if I recall correctly, the IFU states that the product does not degrade.

Yes, it says under the action section on the last page, "The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes."

Q. Okay. Let me go back to your first point on the patient factors. What specific patient factors are you talking about there

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for inclusion under warnings?

A. For example, if there's any potential scarring already there as a result of prior surgeries, information of that nature.

Q. Okay. Anything else under warnings that you're going to opine about ought to be in the TVT-O IFU as of 2010?

A. With regard to the I think -- or I should say with regard to "Chronic pain may result from foreign body reaction and/or scarring and contraction," the information that's provided there, if asked, I would also opine that that scarring and contraction in addition to pain may also result in vaginal tightening and distortion of the vagina.

Q. Okay.

A. And as regards the dyspareunia, occurring and being persistent --

Q. I'm sorry. Where are you?

A. Also on top of page 80.

Q. Oh, "De novo dyspareunia may occur and be persistent"?

A. Yes. That -- that sexual function

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may be affected for a lifetime. There's the potential that sexual dysfunction --
Q. You're just adding length --
A. Between that and the vaginal tightening and narrowing, that between both of those, that there's the potential that a patient would not be able to have sexual intercourse.
Q. Okay. Anything else?
A. As I sit here today --
Q. I know you're trying hard. You've got to come up with one more. That's the best you've got right now?
A. Yes.
Q. All right. Let me switch gears on you for a minute, and I want to talk to you about sources of information other than the IFU for doctors. Okay?
A. I understand.
Q. Would you agree that professional education could be a source of information with respect to the risks associated with the TVT-O?
A. Yes. It's not the primary source. It is a source.

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Q. Okay. And while I'm on that, I did not see any opinion of yours in your report as to professional education.
Do you intend to offer any opinions in the Jennifer Ramirez case about professional education?
A. If I understand your question, you're separating professional education separately from the professional labeling which is addressed in my report.
Q. Oh, yeah. You and I have talked about the IFU, and I am sure we will again.
A. No, no, not that. There's a section in my report that also talks about the promotional labeling.
Q. Marketing pieces?
A. Yes.
Q. Yeah. I'm not talking about that. I'm talking about the actual training sessions, actual professional education where slide decks are shown and cadavers are used. I didn't see any opinions of yours on what I'm calling Ethicon's professional education.
Do you intend to offer any opinions

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on Ethicon's professional education, as I've described that term to you?
A. As I sit here today, no.
Q. Okay. Do you agree that doctors can get information about surgical treatment of SUI including the use of TVT-O from medical school training?
A. Yes.
Q. All right. Depending on --
MR. GOSS: Objection. Form.
MS. VERBEEK: Objection.
THE WITNESS: Depending on the medical school and what the training program is and how extensive their involvement is.
BY MS. SUTHERLAND:
Q. Do you know if the TVT-O procedure is taught in medical school?
A. I don't know that it would be taught in medical school so much as it might be taught in residencies.
Q. Okay.
A. But I haven't -- I can't say that specifically. I've not studied it.
Q. Would medical literature be another

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source of information for doctors about risks associated with surgical treatment of SUI including TVT-O?
A. Yes.
Q. Would talking to colleagues be another source of information for doctors?
A. Yes, but it would be based on an individual doctor's experience, not on -- those are all separate sources, but not the primary sources.
Q. Yeah. And what I'm talking to you about are just different sources where doctors can get information about risks and benefits of different surgical options for the treatment of SUI including the option of the TVT-O; right?
A. Yes.
Q. All right. And, in fact, a surgeon's own clinical experience can be a source of information for him?
A. Yes, although that's limited experience, and, you know, there is documentation now in the literature that supports that doctors performing these procedures with mesh may actually not even

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know the complications with their own patients because many times patients who have complications don't return to the doctor who did the implantation, such as in the case with Ms. Ramirez.

She didn't return to Dr. Reyes to do her revision. She went to other physicians for her revisions. And so that happens, and when that happens, doctors are not aware that their patients have had complications.

(Mr. Goss exits the proceeding.)

MS. SUTHERLAND: I'm going to move to strike everything after "yes."

BY MS. SUTHERLAND:

Q. Do you agree that -- should I wait for him to come back?

A. Probably.

MS. SUTHERLAND: Let's go off.

THE VIDEOGRAPHER: Going off the record. The time is approximately 1:54 p.m.

(Recess taken from 1:54 p.m. to 1:54 p.m.)

THE VIDEOGRAPHER: Back on the

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record. The time is approximately 1:54 p.m.

BY MS. SUTHERLAND:

Q. All right. Dr. Pence, do you agree that doctors who implanted the TVT-O may have learned of the risks of that device through means other than the IFU?

MR. GOSS: Objection. Form.

MS. VERBEEK: Same objection.

THE WITNESS: Some doctors may have learned of some of the risks through other means, but that, again, would be an assumption. It's not the primary means of communicating risks to the doctor. The primary means is the IFU. So one can't rely on a doctor having learned about the risks on -- based on other sources.

BY MS. SUTHERLAND:

Q. Okay. I'll move to strike everything after your first phrase.

Are you aware that some doctors don't read the IFU before implanting surgical mesh?

MR. GOSS: Objection. Form.

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THE WITNESS: Dr. Reyes did.

BY MS. SUTHERLAND:

Q. Are you aware that some doctors do not read IFUs before implanting surgical mesh?

MS. VERBEEK: Objection. Form.

MR. GOSS: Objection. Form.

THE WITNESS: There may be some doctors who don't. But without asking every doctor, I can't say that. And irregardless, whether that happens or not, it's the manufacturer's responsibility to be sure that the IFU is -- contains all the necessary information for safe and effective use of the product, and it's truthful and accurate and not misleading.

BY MS. SUTHERLAND:

Q. Okay. I'm going to move to strike everything after your first phrase and response.

In your opinion, how often should a doctor read a device IFU?

MR. GOSS: Objection. Form, foundation.

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MS. VERBEEK: Same objection.

BY MS. SUTHERLAND:

Q. Or do you have an opinion on that? You may not. I don't know.

A. Dr. Reyes testified he went back to it many times and reviewed it. It definitely should be reviewed any time there's new information that is important to the doctor.

Q. How would a doctor know there's new information if he doesn't review it?

MR. GOSS: Objection. Form.

THE WITNESS: Well, if there's an IFU in every mesh package, and if the manufacturer wants to ensure that the physician knows that there is an update that's important for him or her to know, then a red card, for example, there are different means where that can be attached with a new IFU that says, "Please refer to section adverse reactions and warnings when new information has been added for the safe and effective use of this product" or some similar wording, or a Dear Doctor

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letter can be sent out saying, "We've updated the IFU. Here's a copy. This is the information that's changed. We feel it's important for you to know that."

BY MS. SUTHERLAND:

Q. How many Dear Doctor letters have you seen from pelvic mesh manufacturers?

MR. GOSS: Objection. Form.

THE WITNESS: I've seen at least one. I don't recall how many total I've seen but --

BY MS. SUTHERLAND:

Q. The one you're recalling, was that in relation to updated labeling?

A. It was, if I'm recalling correctly, in relation to this 2011 public -- the advisory committee meeting, FDA advisory committee meeting, and there may have been one as well with regard to removing certain meshes from the market.

Q. With respect to 2011 Ad Com meeting, who sent out that Dear Doctor letter?

MR. GOSS: Objection. Form.

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BY MS. SUTHERLAND:

Q. Which manufacturer?

A. As I sit here today, to the -- I would need to check my memory.

Q. Okay. Do you know whether or not it was Ethicon?

A. I think it may have been Ethicon, but I would need to confirm my memory.

Q. Would you trust me if I said it was?

A. Yes.

MR. GOSS: Doesn't sound like them.

MS. SUTHERLAND: Move to strike.

THE WITNESS: However, I think if you have that, we can talk about it as to whether or not the information in there was exactly what should have been included.

BY MS. SUTHERLAND:

Q. When was Ms. Ramirez implanted?

A. In -- if I recall correctly, it was September of 2010.

Q. All right. Now, have you done any

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study of surgeons who conduct surgical repair of SUI to determine what risks they're aware of, not from reading the IFU, but from their medical school or residency training?

A. Have I conducted a survey?

Q. Right.

A. I've not conducted a survey, no.

Q. All right. Have you conducted a survey of surgeons trained in the surgical treatment of SUI to determine what risks of a mesh device they understood, not from reading the IFU, but from their professional education training?

A. Can you just repeat the question, please?

Q. Yeah, it's a long one.

A. Yes, I know.

Q. Have you conducted any study or survey of surgeons trained in the surgical treatment of SUI to determine what risks of the TVT-O they understood, not from reading the IFU, but from participating in professional education?

MR. GOSS: Objection. Form.

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THE WITNESS: I've not. As regards to a particular survey, I've not conducted such a survey.

BY MS. SUTHERLAND:

Q. All right. Have you conducted any study or survey of surgeons trained in surgical treatment of SUI who implanted TVT-O to determine what risks of the TVT-O they understood from reading medical literature as opposed to reading the IFU?

MR. GOSS: Objection. Form.

THE WITNESS: No, I haven't, and it's not relevant to my opinion as to what should go into the IFU. My opinion would be the same regardless of what the answer to any of those surveys would be because, again, the IFU is the primary communication between the doctor and the surgeon -- I mean, between the company and the surgeon.

BY MS. SUTHERLAND:

Q. And I move to strike everything after "No, I haven't."

Last one on that. Have you conducted any study or survey of surgeons

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trained in the surgical treatment of SUI to determine what risks of the TVT-O they understood, not from reading the IFU, but from their own clinical experience implanting the TVT-O?

MR. GOSS: Objection. Form.

MS. VERBEEK: Same objection.

THE WITNESS: Again, the -- whether or not I -- the answer to any such survey would not impact my opinion as to what should be in the IFU, and I've not conducted such a survey. But also to that point, their own clinical experience may not be representative of the risks of the points I mentioned a little while ago that patients who experience serious complications, and it's reflected in the literature, do not often return to the implanting clinician.

So the implanting surgeon would not know about those risks. So their experience may not be a very accurate reflection of what the complication rate is, and it would be foolhardy to rely on

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their experience only.

BY MS. SUTHERLAND:

Q. All right. I'm going to move to strike.

Is the answer to my question that you have not conducted any such survey or study?

MR. GOSS: Objection. Form.

THE WITNESS: Yes, for the reasons I mentioned.

BY MS. SUTHERLAND:

Q. Okay. Talking about different studies, do you agree that there are more clinical studies evaluating safety and efficacy of TVT than any other device used to treat SUI?

MR. GOSS: Objection. Form.

THE WITNESS: I think, actually, that's from your report. That's my understanding, yes.

BY MS. SUTHERLAND:

Q. All right. Do you have an understanding that there are over 100 RCTs or randomized control trials for TVT?

A. That's my understanding.

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MR. GOSS: Objection. Form.

BY MS. SUTHERLAND:

Q. All right. And there are over 60 RCTs or randomized control trials for TVT-O?

MR. GOSS: Objection. Form.

THE WITNESS: Yes, not necessarily conducted by Ethicon.

BY MS. SUTHERLAND:

Q. And is it your understanding that there are over a thousand studies -- I'm not saying RCTs but over a thousand studies on TVT?

MR. GOSS: Objection. Form.

THE WITNESS: I have seen that number, yes.

BY MS. SUTHERLAND:

Q. Okay. Have you looked at the patient brochure for the TVT-O in this case?

A. My understanding that Ms. Ramirez, if I'm recalling correctly, does not recall having received a brochure, although I believe, to the best of my recollection as I sit here today, Dr. Reyes thought he would have given her one, but she did not recall -- if I'm recalling correctly, she

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did not recall having received one.

Q. All right. I thought I was done with these questions. A couple more.

Have you conducted a study or survey to determine whether the inclusion, for instance, of your bullet points for the adverse reactions on pages 78 to 79 in the TVT-O IFU would have changed any doctor's decision to implant TVT-O?

MS. VERBEEK: Objection to form.

MR. GOSS: Objection. Form.

THE WITNESS: You're speaking about just the adverse reactions, or you're talking about the warnings as well?

///

BY MS. SUTHERLAND:

Q. Well, for now for my question, let's look at just the adverse reactions and -- let me ask it again to make sure I've got it clean.

Have you done any kind of study or survey of surgeons trained in the surgical treatment of SUI to determine whether or not

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the inclusion of your listed adverse reactions on pages 78 to 79 of your report would have changed their decision to implant TVT-O?

MR. GOSS: Objection. Form.

THE WITNESS: I've not done a survey.

MS. VERBEEK: Objection.

BY MS. SUTHERLAND:

Q. Okay. In your report, I think it's on page 60, you list out what was listed in the FDA's public health notice from 2008, if you want to turn to that.

A. Which page?

Q. Page 60.

A. Page 60.

Q. And I'm actually just curious about this. Is it your opinion that the complications that the FDA listed in its 2008 PHN --

A. You're on page 60?

Q. Yeah. Are you not there?

A. My page 60 is Section 7 "TVT Classic and TVT Obturator: Known/Knowable Risks."

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Q. Uh-huh.

A. And you said something about the --

Q. And then you've got -- yeah -- your paragraph talks about --

A. Oh, you're talking about -- I see. I have a section on FDA. I thought you might be in that section. I'm sorry.

Q. No, no, no. Let me make sure -- I thought I had this right. Are the bullet points that you've listed there on pages 60 to 61 the adverse reactions listed by the FDA in its PHN in 2008?

A. Yes.

Q. Okay. Now, is it your opinion that if an IFU in 2008 had included these bullet points in its adverse reactions, that it would have been adequate or inadequate?

MR. GOSS: Objection. Form.

THE WITNESS: No. It still would have been inadequate. At this point in 2008, you know, what I've stated here is that Ethicon knew about all of the following complications identified in the 2008 PHN, and I've listed the ones that they testified they

Page 200

have known about.

But remember, the public health notification was based on an evaluation of the MAUDE database. And so this was information coming from one of the sources of information that was available for identifying potential risks with the TVT-O and other sling -- polypropylene slings.

BY MS. SUTHERLAND:

Q. They look at literature too; right?

A. That was in 2011. They did -- you're talking about now about the 2008 public health notification.

Q. Yeah. Are you saying FDA had not reviewed literature for the risks associated with pelvic mesh --

A. The 2008 public health notification --

(Simultaneous discussion interrupted by the reporter.)

MR. GOSS: She's going to have a long enough day as it is. Let's try to not step on each other.

THE WITNESS: I'm sorry. The

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2008 public health notification, to the best of my recollection, and I can just verify that, was based on a review of the MAUDE database.

It was in 2011 that the FDA conducted an evaluation of the scientific and medical literature from 1996 through 2011. So what I'm saying is that the 2008 public health notification was based only on one source of information, whereas Ethicon had available to it not only its own internal documentation where a number of different ones of its senior staff have testified that all of these risks were known about at the time of launch, but also they had available to their own internal complaints, and there are, in their own internal complaints, their issue reports, a number of issues that, in my opinion, a number of adverse reactions, in my opinion, that should have been submitted as MDR reports but that were not.

FDA didn't have access to

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those. The company did as well as the scientific and medical literature as well as the information from the experts and with their summit meetings, with the experts that they met with.

They had -- that's why the manufacturer is the greatest repository of the information related to their own product. So this information definitely should have been in there, but there was more beyond that that should have be included.

BY MS. SUTHERLAND:

Q. I'm going to respectfully move to strike that answer and the previous answer after "No, it was not adequate" because I think my question to you was: Was this listing by FDA in 2008 of adverse reactions adequate had it been in an IFU for a pelvic mesh device in 2008?

A. No, for the reasons I explained.

Q. All right. Was mesh erosion a well-known complication in 2008?

A. Yes.

Q. All right. Was infection a

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well-known complication in 2008?

A. Yes.

Q. Was pain a well-known complication in 2008?

A. Yes. You're talking about well known to the company?

Q. No. I'm talking about well known to users of the device such as a TVT meaning --

A. I'm talking about well known to the company.

Q. Was mesh erosion well known to users of surgical -- of mesh devices, pelvic mesh devices, in 2008, or do you know?

MR. GOSS: I'm going object to the form of the question.

MS. VERBEEK: Objection. Form.

MR. GOSS: You're unclear as to well known to who?

BY MS. SUTHERLAND:

Q. Now do you know I'm talking about surgeons that are trained in the surgical treatment of SUI?

A. I can't tell you --

MR. GOSS: Objection to form.

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MS. VERBEEK: Form.

THE WITNESS: -- what every surgeon -- what was well known to every surgeon. That's the reason the information -- I keep going back to the purpose of the IFU and the reason that information has to be in the IFU. The company was well aware of these, as is noted here in my report.

There are a number of senior employees, senior executives at Ethicon that have testified that all of these -- all of this information was known to Ethicon at the time of launch. And in my own analysis, which I presented in my report, I did the analysis as to what was known at time of launch based on MAUDE database, based on internal documentation, deposition testimony, based on the scientific literature, and I was able to make that analysis of everything that should have been in the IFU at time of launch back in, 2000 -- end of 2003, 2004 and was missing.

BY MS. SUTHERLAND:

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Q. I'm going to move to strike everything after "No, I can't tell you what was known by surgeons."

Is it your opinion that the adverse reactions that were listed in the FDA's 2008 PHN were listed according to the descending order as set out in the Blue Book Memo?

MR. GOSS: Objection. Form.

THE WITNESS: Do you have a copy of the 2008 public health notification with you?

BY MS. SUTHERLAND:

Q. I do not. Tim might.

MR. GOSS: I might. Give me one second and I can get it for you. It's next door.

MS. SUTHERLAND: Actually, let's take a break.

THE VIDEOGRAPHER: With the approval of counsel. Going off the record. The time is approximately 2:14 p.m.

(Recess taken from 2:14 p.m. to 2:27 p.m.)

THE VIDEOGRAPHER: With the

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approval of counsel, back on the record. The time is approximately 2:27 p.m.
BY MS. SUTHERLAND:
Q. Dr. Pence, I had marked the 2008 PHN as Exhibit Number 11.
Do you have that in front of you?
A. I do.
(Exhibit Number 11 was marked for identification.)
BY MS. SUTHERLAND:
Q. All right. And now, am I correct that that PHN sets out certain complications associated with pelvic mesh?
Do you see that?
A. Yes, I do.
Q. All right. And now, is it your understanding or is it your opinion that the complications that are listed in that paragraph starting "The most frequent" are actually listed in the appropriate order under the Blue Book Memo?
MR. GOSS: Objection. Form.
THE WITNESS: Yes. And I was just going to make that point that you can see that FDA lists the most frequent

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complications, and that's what they relied on, and I wanted to just verify that in the 2008 PHN, it did note that those were the most frequent.
It's also reflected -- if you look in my report on page -- let me find it again. On page 117, I have a tabular presentation of the number percent of adverse events for SUI reported to MAUDE from 2008 to 2010, which was the data that was reflected in the 2000 -- FDA's 2011 safety communication.
And you can see there that the numbers of reports of pain, erosion, and so forth and you can see the order of frequency. And the total number of -- the total number of reports included for SUI in that MAUDE evaluation was 1371. So you can see the percent of those 1371 reports that included pain. It was 34.9 percent.
So for the 2008 to 2010 data, you can see that the listing of the most frequent complications is very similar to the listing in the 2000/2008, which

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was based on data from 2005 to 2007, if I recall correctly.
BY MS. SUTHERLAND:
Q. And while we're on that, let me ask you something while you're on page 117 of your report. Were you able to duplicate a search of the MAUDE database and come up with the 1371 total number of MDRs like the FDA did?
A. I didn't look at all nine manufacturers. I have shown and I show on my report for TVT and TVT-O what the numbers of reports of these particular events are and how they are representative in the order of frequency of the adverse reactions for those two devices are representative of the nine manufacturers' events that were -- I believe it was nine manufacturers, if I recall correctly as I sit here today, that were included in FDA's assessment.
Q. Okay. I don't think you answered my question.
A. I think I understand your question. I think I did. I think I said I haven't looked at all nine manufacturers.

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Q. So you have not attempted to duplicate FDA's search to come up with the 1371 that FDA came up with that's listed in the PHN; correct?
A. No, not that specifically. I relied on FDA's evaluation for that. But what I did do as relevant to my report is look into TVT and TVT-O to see how the data for TVT and TVT-O compared to FDA's data across the multiple manufacturers. And to that point, in one of the reports, FDA noted that the -- there did not seem to be a difference across the types of events that were reported across manufacturers.
Q. Okay. Let me ask it again. Did you try to duplicate FDA's search that they listed actually in their 2011 safety update where they listed a total number of SUI reports being 1,371?
A. No. I specifically looked at certain manufacturers and certain products for those manufacturers.
Q. When you're looking at your Table 9.1 on page 117 --
A. Yes.

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Q. -- and you have there pain, 479 number of reports of pain.
Do you see where I am?
A. Yes.
Q. And then you say that's 34.9 percent.
Do you see where I am there?
A. Yes.
Q. You are saying that 479 number of reports of pain is 34.9 percent of the 1371?
A. Yes.
Q. All right. But let me ask you this. Did FDA find 479 reports of pain out of their 1,371?
A. I believe this information came directly from their report, yes. That was their finding.
Q. From the 2011 safety update?
A. Yes. Based on their review of the MAUDE database from 2008 to 2010, to the best of my recollection as I sit here today. Let me just take a look and confirm.
Q. I didn't recall the 2011 safety update setting out the number of reports of pain, the number of reports of erosion.

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A. You have to look at the executive summary and the information behind that that FDA --
Q. Is that where the numbers are coming from?
A. To the best of my recollection, that's correct. I probably have it footnoted. Let me -- to the best of my recollection as I sit here today, that's where that -- those are FDA's numbers, not mine.
Q. Okay. And then, if I'm understanding you correctly, if you turn to page 123 of your report --
A. Yes.
Q. -- are you saying that, for instance, on the row of pain going across there --
A. Yes.
Q. -- that TVT, TVT-O reports are 228 of those reports out of those 479?
A. That's correct.
Q. All right. Did you do a search and find 479 reports of pain out of which you culled the TVT/TVT-O reports of 228?

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A. No. I took -- I took FDA's numbers that they presented, which, again, if I recall, and I believe it's in my report, but if I recall correctly as I sit here today, this was across nine manufacturers, and I can look it up and verify that as well.
But I looked at TVT and TVT-O for that same time period, 2008 to 2010 --
Q. Yeah.
A. -- and found for TVT and TVT-O, 228 reports of pain. And as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, according to FDA's numbers.
Q. Right. But my question to you is: What search did you run to find pain in the TVT/TVT-O reports, and how does that search compare to what FDA ran to find 479 reports of pain in order to make your percentage valid?
A. I downloaded the MAUDE --
MR. GOSS: Objection. Form.
THE WITNESS: We downloaded the MAUDE database and pulled from the MAUDE database and got -- in one of the

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exhibits, it describes the methodology that we used to download the MAUDE database. And from the MAUDE database, there -- in all the MDR reports, there's an event description, and we went through each individual event description and pulled out every one after removing duplicates --
BY MS. SUTHERLAND:
Q. I'm going to ask you about that.
A. Removing duplicates, pulled out the numbers of reports of pain. And, for example, and I think it's important to note, if there was more than -- if more than one type of pain was reported for a particular patient, for this number, only -- the patient was only recorded once as a patient having pain.
So we're not saying that this is -- this is 228 patients is the point I'm trying to make who experienced one or more types of pain. And we -- FDA analyzed their own MAUDE database and looking at their own database, they came up with 479 reports across the nine manufacturers that they

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looked at, and from analyzing the very same database for TVT and TVT-O only, we found 228 reports.
Q. Yeah. And I follow that. But my question is: Did you do any kind of quality check with the searches you were running to find the TVT and TVT-O reports of pain to ensure that you would have also found only 479 reports of pain like the FDA found?
A. If I understand your question as you've asked it, the evaluation that we did is accurate. We didn't then try to validate that FDA evaluated their own database accurately.
Q. Or even ran the same search that you did to try to find the same number of reports. Fair?
A. Well, we downloaded TVT and TVT-O and any terms that were -- any like TVT obturator, TVT-O, TVTO, we looked at everything that was TVT, TVT-O. There are different ways that something may be represented. You know, the reports may represent, for example, TVT-O in a different way. TVT may be TVT or TVT classic or TVT

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retropubic.
There are various ways in which the information may be, by product, recorded, but it's all TVT or all TVT-O. We downloaded all of those that were TVT and all that were TVT-O.
Q. I got that part.
A. I understand.
Q. My question is: How are you validly comparing it to FDA's number of 479 total complaints of pain without knowing what terms and how FDA did that search to see if you'd come up with the same number of total complaints of pain that FDA did?
A. Well, FDA did this across nine manufacturers. I did not try and duplicate FDA's data, but FDA said that this is what they found in their own MAUDE database, and I looked at the same information for the same time period for TVT and TVT-O. So if FDA's numbers were wrong, then --
Q. Or just different because they ran a different type of search than you did. Isn't that possible?
A. If you're downloading all nine

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manufacturers, then they're trying to be comprehensive. Then it may be more. I mean, there are more than nine manufacturers; so they looked at nine manufacturers.
Q. And if I'm understanding this chart that you have on 123, you are assuming in order to reach your percentage of all SUI mesh reports, that last column?
A. Yes.
Q. You are assuming that your number of reports for your TVT-O column came out of the very same number of all mesh product reports that FDA found?
A. State that last sentence again.
Q. Sure. For instance, in order to reach your number here on your chart on the first column that the percentage of TVT and TVT-O reports of pain for all SUI mesh reports is 47.6 percent, you are assuming that this number of TVT and TVT-O reports of 228 came out of this number, 479.
Aren't you making that assumption?
A. Not exactly.
MR. GOSS: Objection. Form.

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THE WITNESS: I don't use the word "assume," and I'm not using it for that basis. I'm saying that of 479 reports that FDA reported and with Ethicon and TVT and TVT-O being one of the major manufacturers, that if you look at that number and you look at what we were able to download for TVT-O, using that number, those numbers alone standalone, but I wanted to compare what percentage based on the total that FDA had found, and if you look at the total that FDA reported, I'm not assuming how they did except that they said across nine manufacturers, and one they based a public health notification on this information.
I didn't try and duplicate that data, if that's what you're asking. But I didn't -- I looked at this based on 479 reports that they said they found across the manufacturers that they looked at that I found this many reports. And that would be 47.6 percent as the total.

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BY MS. SUTHERLAND:
Q. Yeah. And my question just is: I mean, aren't I correct that in order to get your 47.6 percent of pain, that you're taking that 228 number of TVT/TVT-O reports and doing some sort of division with this 479 number from FDA?
A. Yes, that's correct.
Q. All right. And am I also correct that you didn't do some sort of quality check to ensure that you would have found the same number of reports, meaning 479, with your search terms that you used to find the TVT and TVT-O reports of pain?
MR. GOSS: Objection. Form.
THE WITNESS: Let me check one thing here quickly. It was in the 2000 -- I just wanted to double-check my figure of nine. It was in the 2008 FDA public health notification that they noted that the reports of complications were from nine surgical mesh manufacturers of surgical mesh devices used to repair pelvic organ prolapse and stress urinary incontinence. That's

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where the nine. I just wanted to verify the nine manufacturers.
Now to your specific question, I did not verify FDA's numbers, but I think maybe there's a disconnect in understanding that we pulled everything for TVT and TVT-O that we could find.
BY MS. SUTHERLAND:
Q. No, I got that.
A. And FDA pulled the information that it found for manufacturers that made SUI mesh products.
Q. And I got that.
A. And I didn't verify that FDA did their analysis correctly. I think that's what you're asking to do my percentage.
Q. No. I'm not asking whether or not FDA did it correctly. What I'm asking is whether or not you ran a similar search for pain as FDA did for pain when you were finding your TVT and TVT-O reports.
MR. GOSS: Objection. Form.
THE WITNESS: Yes, I did for TVT and TVT-O.
BY MS. SUTHERLAND:

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Q. Did you run -- well, tell me what search you ran for TVT and TVT-O to allow you to come up with 228 reports of pain.
A. It's in the exhibit -- it's in the Exhibit 1, I believe, to my report that gives you -- that shows you the methodology, and it also provides a tabular presentation for TVT and TVO by year of the numbers of reports.
Q. Yeah, and maybe I can cut to the chase. Did you do a term search for "pain" to come up with the 228 MDRs?
A. What you have to do in that -- when you're doing a manual download, you have to read through every event description, and we downloaded the information into an Excel database, and then you have to read through every event description to pull out the adverse events that are reported, and then we tabulated those in Access and did an assessment of total number of pain.
Q. Okay. And so how are you able to tell me that the way that you did your analysis to pull out the 228 reports of pain for TVT and TVT-O would have gotten you the

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same number that FDA got had you done it for all nine mesh manufacturers, the same number being 479?
A. Well, the information, whether I'm reviewing it or FDA is reviewing it, the information that is in the event description doesn't change, and that's where the information is located.
Q. I guess what I'm getting at is do you know if a report listed pain, erosion, and infection, did FDA put that report in each separate row there for pain, erosion, and infection? Or did it pick one and say, you know what? For this report, I'm going to put it just in erosion?
MR. GOSS: Objection. Form.
THE WITNESS: Ethicon picked one.
BY MS. SUTHERLAND:
Q. Well, I'm asking do you know how FDA did it so that you can say that your percentage in this last column is valid based on you and FDA performing the same search to reach the same numbers?
MR. GOSS: Objection. Form.

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THE WITNESS: Do you have the executive summary? With -- my recollection is this is the total number of patients in which they found pain, and they would have counted those appropriately. They would have accounted those separately. I don't recall, as I sit here today, without going back and looking at the information. I don't recall exactly how -- what they described as their methodology, but having done many adverse event assessments over the course of my career, if you -- if a patient has pain and erosion and infection, you don't just choose one of them. You report every one.

BY MS. SUTHERLAND:

Q. And do you know if that's what FDA did in order to reach their numbers in that first column on page 123?

A. To the best of my recollection as I sit here today, that is correct, but I would need to go back and review that. If you have it, I'd be happy to take a look at it.

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I just -- I can't recall specifically that without looking back at the document.

Q. Did you make an attempt to perform your search and inclusion of reports in the same manner that FDA had as set out in what you're telling me is in the executive summary?

MR. GOSS: Objection. Form.

THE WITNESS: I did the most comprehensive assessment we could do, which was to pull all the MDR reports for any description of TVT, any description of TVT-O, remove duplicates, and read through the event description, and every adverse event that was noted was recorded, and then our tabulations were done based on that.

With the point also that I was making that if the patient had several different types of pain reported, we didn't report that patient twice. We reported, and you'll see in the exhibit that you can see the total numbers of reports of pain versus the total numbers of patients with pain.

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For this number, the numbers of patients with pain was exactly that. The number of patients with pain, not the number of episodes of pain. As I note here, the total number of reports is greater than the number of MDRs because most MDRs reported more than one adverse event.

BY MS. SUTHERLAND:

Q. Okay. I think I'm going to move to strike that answer.

Would you read my question back.

(Record read by the reporter as follows:

THE WITNESS: I think I answered that. I think I told you --

MR. GOSS: Wait, wait. The ball is in her court.

THE WITNESS: Sorry.

BY MS. SUTHERLAND:

Q. Can you answer that question?

MR. GOSS: That's what you get.

THE WITNESS: Sorry. I think I -- I answered that. I said that -- I've answered that in the last couple of

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questions. If you have the document that describes FDA, what FDA did, I can go back and just verify my recollection. Without that document, I'm giving you the best information I can with regard to my recollection --

BY MS. SUTHERLAND:

Q. Okay.

A. -- as to how FDA -- what FDA did. What we did, you can't be more comprehensive than what we did --

Q. I know you're comprehensive.

A. -- for looking at TVT and TVT-O, and it was a very laborious process to go through each of these, and we were as conservative as possible, like removing duplicates, and clearly, and that's the appropriate way to report adverse events.

You don't -- you know, if you're looking at total number of patients with pain, you don't count a patient twice if they had two different types of pain. So I followed the same methodology that I've employed in the course of my consulting career for medical device pharmaceutical

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companies.
Q. Let me just close the loop on this just to be sure I have it in my head. Let me pick another column here. Let's say bleeding. In order to reach this 39.8 percent in the last column, what you're saying, as I understand it, that is the total percent of reports attributed to TVT and TVT-O out of all SUI reports from 2008 to 2010?
A. According to FDA's number of the number of patients that -- the number of MDR reports, I should say, which should be individual patients, had bleeding. There were 103.
Q. Right. And let me stop you there because, as I understand it, you did not do the same search that FDA did to come up and verify that you also would find 103 reports?
MR. GOSS: Objection. Form.
THE WITNESS: Yes. I did not look at all the other manufacturers. That's correct.
BY MS. SUTHERLAND:
Q. Okay. So you're assuming in order

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to reach this 39.8 percent that your number of 41 reports comes out of this number, 103 reports?
MR. GOSS: Objection. Form.
THE WITNESS: Based on the number of bleeding reports that FDA reported, we took a percentage of that to arrive at what percentage of that number was TVT and TVT-O.
BY MS. SUTHERLAND:
Q. Okay. I'm going to change gears.
A. Okay.
Q. And get back on my outline.
Has the FDA ever said that the TVT-O IFU up to the time of implant in this case was inadequate?
MR. GOSS: Objection. Form.
THE WITNESS: I'm not -- there may be internal communication to which I've not seen, but based on what I've seen, the answer to that is, no.
BY MS. SUTHERLAND:
Q. All right. Let me ask it cleanly. As far as documents that you have seen -- and we've talked about the number of

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documents that you've seen, and you claimed it's a lot, from that number of documents you've reviewed, has FDA ever said that the IFU for the TVT-O up to the time of implant was inadequate?
A. You know, the way I'm going to answer that is I have not seen -- while I have not seen any specific communications directed to Ethicon, the 2008 public health notification includes information that -- and recommendations that indicate what a manufacturer should do and recommendations for what physicians need to know.
Q. Where are the recommendations that the FDA said a manufacturer ought to do with respect to its IFU in the 2008 PHN?
A. The IFU is a communication, as we've discussed before, the primary communication between the manufacturer.
Q. Now, I want you to answer my question.
A. I am. But it has a basis, and the basis is that it is the manufacturer's communication with the physician, and these recommendations say that the physician

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should be vigilant for potential adverse events, especially erosion and infection, watch for complications associated with the tools, inform patients that implantation of surgical mesh is permanent, that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication, inform patients about the potential for serious complications and their affect on quality of life, including pain during sexual intercourse, scarring and narrowing of the vaginal wall, noted there in POP repair, and provide patients with a copy of the patient labeling from the surgical mesh manufacturer.
There is testimony by Ethicon, and if I recall correctly as I sit here today, specifically from Dr. Hinoul testifying that all of the information in the 2008 public health notification was included in the TVT and TVT-O IFU, and it was not.
But that information -- and I think it maybe even -- that publicly, if I'm recalling correctly as I sit here today -- I

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can actually verify that.
Q. I've got to say you're not answering my question.
A. Oh, I am answering your question because the fact that physicians should do these things, it's up to the manufacturer to communicate this information to the physicians through the IFU.
So while this is a public health notification, and the FDA is telling the physicians what the manufacturer should have told the physicians.
Q. Is there a document where the FDA ever told Ethicon your TVT-O IFU is inadequate up to the date of implant?
MR. GOSS: Objection. Form.
THE WITNESS: I believe I've answered that.
BY MS. SUTHERLAND:
Q. You're pointing to the PHN?
A. I'm pointing to the PHN.
Q. Is there anything besides the PHN that you can point me to where you're saying FDA told Ethicon the TVT-O IFU is inadequate?

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A. If you read the 2008 public health communication and you compare --
Q. I said other than --
A. I know, but if you compare that -- I can't tell you about a specific document from FDA to Ethicon, but if you compare what's supposed to be notified to physicians and the IFU, they're vastly different.
Q. All right. Is the word or the letters "IFU" anywhere in the 2008 PHN?
MR. GOSS: Take your time and review it.
MS. SUTHERLAND: And it's a page and a half.
MR. GOSS: We can take 30 minutes.
BY MS. SUTHERLAND:
Q. That's a yes or no.
A. There is no mention of the IFU specifically in this document.
Q. All right. Is the word "Ethicon" anywhere in this document, the 2008 PHN?
A. No, but it addresses reports from nine surgical mesh manufacturers which were the basis for this, and so Ethicon was

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included.
Q. Move to strike everything after "no."
Is the TVT-O mentioned anywhere in the 2008 PHN by name?
A. Not by name.
Q. All right. Has FDA ever issued a warning letter to Ethicon about the TVT-O?
A. No, not that I -- not that I've seen, and I have looked, yes.
Q. I bet you looked.
We're at 30 minutes. Do you want to go off and check?
A. Yes, please. Thank you.
THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately 3:00 p.m.
(Recess taken from 3:00 p.m. to 3:09 p.m.)
THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 3:09 p.m.
BY MS. SUTHERLAND:
Q. Dr. Pence, have you ever seen a

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document where FDA determined that the TVT-O device was misbranded?
MR. GOSS: Objection. Form.
THE WITNESS: No.
BY MS. SUTHERLAND:
Q. All right. In fact, as far as you know, FDA has never determined TVT-O to be misbranded; correct?
MR. GOSS: Objection. Form.
THE WITNESS: I've never seen any documentation stating that.
BY MS. SUTHERLAND:
Q. Stating that it is misbranded?
A. Correct.
Q. All right. Have you ever seen any documentation from FDA stating that TVT-O is adulterated?
MR. GOSS: Objection. Form.
THE WITNESS: No, I have not.
BY MS. SUTHERLAND:
Q. All right. Has FDA ever requested the TVT-O to be withdrawn from the market?
MR. GOSS: Objection. Form.
THE WITNESS: No.
BY MS. SUTHERLAND:

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Q. Has FDA ever recalled the TVT-O?
A. Not to my knowledge, as I sit here today.
Q. All right. Have you ever spoken -- have you ever spoken with a woman who had the TVT-O implanted in her?
MR. GOSS: Objection. Form. Foundation.
THE WITNESS: Yes.
BY MS. SUTHERLAND:
Q. Would that be a plaintiff?
A. Yes.
Q. All right. Which plaintiff?
A. That would have been Ms. Batiste.
Q. Okay. You haven't talked to Ms. Ramirez?
A. No, I have not.
Q. All right. Have you ever done any kind of survey to determine what women perceived from the patient brochure for the TVT-O?
A. No. I have not done such a survey. And just to clarify, Ms. Batiste, I spoke to her in the context of being courteous when I was at trial, but I didn't discuss any

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specifics obviously with her.
Q. Yeah.
For the Class 2 device TVT-O, is there a requirement that Ethicon have a patient brochure?
A. There isn't a requirement unless the FDA requests it.
Q. Okay. Did the FDA request one for the TVT-O?
A. Do you have the 510(k)? I'd have to go back --
Q. I don't have the 510(k).
A. -- and look. They did -- they had --
MR. GOSS: I can probably let you see one.
MS. SUTHERLAND: I don't want to take the time.
Do you recall, as you sit here today, whether or not FDA requested a patient brochure for TVT-O?
THE WITNESS: My recollection is they did not.
BY MS. SUTHERLAND:
Q. Yeah, because it was a special

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510(k); right?
A. It was. My recollection also is, though, that Ethicon had brochures for the TVT family of product at the time of that submission, and, to the best of my recollection as I sit here today, and I can look it up, did not include the patient labeling in the 510(k), and what is intended to be included in a 510(k) would also include patient labeling if a company is going to be using it. Let me just take a moment here to check something.
Yes, as stated on page 92 of my report, the patient brochure was not included for FDA's review in the proposed labeling section of the 510(k) pre-market notification for the TVT-O, although a patient brochure had been available since 2001 for the TVT system, and noting also that the information that is intended to be used required in a pre-market notification, submission includes proposed labeling and advertisement sufficient to describe the device's intended use and its directions for its use -- and the directions for its use.

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Q. Now, at the time of the submission of the TVT-O 510(k), was there in existence a TVT-O brochure?
A. The --
MR. GOSS: Objection. Form.
THE WITNESS: There was -- if you look at my report on page 92, in the documents that were available for my review, there were 16 patient brochures final copy relevant to the TVT-O product with the following dates, and one of those was dated 2004.
The submission went in in 2003, the 510(k) submission went in in 2003, but as I noted, many of these are the TVT family of products and contain very similar information, and my opinion would be that they certainly could have included one in the 510(k) submission. They had TVT ones since 2001 at least.
BY MS. SUTHERLAND:
Q. Let me get an answer to my question, though, because I think my question was, was there in existence at the time of the submission of the TVT-O 510(k) a

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TVT-O brochure? That answer is no, isn't it?
A. The ones that were made available to me began in 2004, which was the same time period they marketed the product.
Q. All right. I'm still not hearing an answer to my question. Was there in existence at the time of the submission of the TVT-O 510(k) a TVT-O brochure?
A. Not one specific to the TVT-O, but there were TVT ones, and as I noted, many of these brochures are not specific to TVT or TVT-O. They are for the TVT family of products.
Q. I'm going to move to strike everything after "Not one specific to the TVT-O."
For those brochures that you're talking about that were for the TVT family of products, they didn't include TVT-O until after TVT-O was cleared by FDA, now, did they?
MR. GOSS: Objection. Form.
THE WITNESS: No, but they could just as the IFU for TVT-O was

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included in the 510(k), because there were brochures that were existing for TVT since very shortly thereafter and for launch, there was a -- there was one that included TVT-O to comply with the -- what should be included in the 510(k), Ethicon could readily have used what it had and made any additions for TVT-O and submitted it in the 510(k) but did not.
BY MS. SUTHERLAND:
Q. I want to move to strike everything after "no."
Based on what was in existence with respect to a TVT-O brochure, are you opining that Ethicon breached some standard or regulation by not creating a TVT-O brochure to include with its 510(k) submission?
MR. GOSS: Objection. Form.
THE WITNESS: Well, as I note in the information and referencing the guidance on medical device patient labeling, which was a 2001 guidance, the information that's required in a pre-market notification submission

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includes proposed labels, labeling and advertisement sufficient to describe the device, its intended use and directions for its use.
So if -- since Ethicon obviously intended to include patient labeling and make that available, it would have been appropriate for them to include patient labeling in their 510(k) submission.
BY MS. SUTHERLAND:
Q. Now, did you see documents that reference an intent by Ethicon to have a patient brochure for TVT-O before clearance of TVT-O?
MR. GOSS: Objection. Form.
THE WITNESS: I don't -- I don't recall specifically, as I sit here today, except to say that they had had TVT patient labeling in existence since 2001.
BY MS. SUTHERLAND:
Q. Okay. Do you intend to offer an opinion as to a safer alternative design for the TVT-O?

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A. If asked, I would offer that opinion.
Q. I mean, do you have that in your report?
A. I talk about mesh fraying, and I talk about the laser-cut mesh versus the mechanically cut mesh and various issues with the mechanically cut mesh.
Q. Would it be your opinion that laser-cut mesh is safer than mechanically cut mesh?
A. The testing wasn't done on the laser -- they both have issues. They both have different issues, and the testing was never done to -- clinically to determine head to head how they compare.
Q. So do you intend to after an opinion that laser-cut mesh is safer than mechanically cut mesh in this trial?
MR. GOSS: Objection. Form.
THE WITNESS: No. I'm saying that there were issues with mechanically cut mesh. There were also issues with the laser-cut mesh, and the testing was never done to assess whether or not,

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with either one, the implications of the issues -- with both what the implications were for the patient.
BY MS. SUTHERLAND:
Q. Move to strike everything after "no."
Are you aware -- let me ask it this way: In 2010 at the time of implant, was there available a mesh sling that, in your opinion, was safer than the TVT-O?
MR. GOSS: Objection. Form. Foundation.
THE WITNESS: Based on -- there were meshes available --
BY MS. SUTHERLAND:
Q. Answer my question now.
A. -- that were considered safer than the heavy weight mesh that is in the TVT-O, and Ethicon had such meshes.
Q. I'm going to move to strike.
Would you read back my question, please?
(Record read by the reporter as follows:
Let me ask it this way: In 2010 at the time of implant, was there available a mesh sling that, in

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your opinion, was safer than the TVT-O?")
THE WITNESS: I've not done an evaluation of all mesh slings that were available; so I can't -- I can't answer that question.
BY MS. SUTHERLAND:
Q. Okay. So you aren't intending to offer an opinion that there was some mesh sling that was available in 2010 that was safer than TVT-O; correct?
MR. GOSS: Objection. Form.
THE WITNESS: As you've asked the question, that is correct. If asked, I will opine that there were meshes available by Ethicon's own documentation and testimony that would -- that they believed would be safer than the heavy weight mesh used in TVT-O.
BY MS. SUTHERLAND:
Q. And are you talking about Ultrapro?
A. BiPro, there are other meshes that were available that were lighter weight in 2004.
Q. Now, have you seen any medical

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literature using those meshes in the surgical treatment of stress urinary incontinence?
A. Those particular meshes?
Q. Correct.
A. Not that I've seen at this point today for Ethicon.
Q. Because there's not any.
A. I know.
Q. Right?
A. That's correct.
Q. All right.
A. Because they didn't develop it for SUI. They didn't take it to that step where they had meshes that could have -- they believed could have been safer but never developed the sling with such meshes.
Q. I'm going to move to strike.
Let's change gears and talk about adverse events. If you'll flip to page 125 of your report, are you with me?
A. Yes.
Q. Okay. Now, in reading your report, as I understand it, you have -- I'm going to talk about these in different buckets.

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A. Okay.
Q. So in my first bucket, I'm going to talk about the reports that you're claiming were reportable but were not given to FDA. Okay?
A. Yes. These are examples.
Q. Examples. Now, you list 29 examples; correct?
A. Yes.
Q. And that is somewhere in your report, and then the full section of the 29 is in Exhibit 4 to your report; correct?
A. Yes.
Q. All right. The first thing I want to ask you is: Are you intending to specify any other issue reports other than the 29 that you specifically delineated that should have been reported to FDA but were not?
A. As I sit here today --
MR. GOSS: I'm sorry I didn't hear the last part of that. Would you ask that again?
MS. SUTHERLAND: I don't know if I can ask it the same way.
MR. GOSS: Can you read it

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back?
(Record read by the reporter as follows:
The first thing I want to ask you is are you intending to specify any other issue reports other than the 29 that you specifically delineated that should have been reported to FDA but were not?")
THE WITNESS: As I sit here today, no.
BY MS. SUTHERLAND:
Q. Okay.
A. If there are some that are presented to me, and I'm asked about them, I would opine about them.
Q. Tell me how you found those 29. What was your methodology to pull out those 29?
A. If you look at page -- at the bottom of page 124, I note that an issue report -- what an issue report is and that there were 862 TVT issue reports from 1999 to 2012 and 901 TVT-O issue reports from 2004 to 2012 that I received and reviewed for the preparation of my TVT and TVT-O reports.
And I was able by matching up

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the -- what was in the MAUDE database to the issue reports, I was able to determine that Ethicon submitted 70 percent as MDR reports to FDA for TVT, and I determined then that 29.9 percent or 258 were determined to be not reportable by Ethicon. And then one was undetermined.
For TVT-O, 444 or 49.3 percent were submitted as MDR reports to FDA and 457 or just over 50 percent, 50.7 percent, were determined by Ethicon to be not reportable.
So I reviewed the issue reports that Ethicon determined to be not reportable, and they showed that -- my review showed that a number of them met the requirements for MDR reporting and should have been submitted to FDA, in my opinion. And I took examples of those that Ethicon determined were not reportable and included those in my report.
Q. All right. Now, are you intending to offer an opinion that some number more than 29 should have been reported to FDA?
A. I don't have a specific number, if I understand your question correctly. I

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don't have a specific number that I'm going to say should have been reported but were not reported but that there were a number that were not reported that should have been reported.
And because of the importance of reporting so that, for example, the 2008 public health notification, if companies are not fulfilling their responsibilities for reporting MDRs according to the requirements for reporting, then that information doesn't populate the database, and FDA doesn't become aware, nor do other people who may be, like physicians, who -- we talked about different sources of information -- who may access the MDR database or patients to see -- because it is a publicly available database to see what information exists. That information is not there.
So it's not a true picture, and we talk about there's a lot of underreporting, and this is one of the reasons there's underreporting. There are other reasons for underreporting to the MAUDE database as well, but FDA, if they get the information

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sooner, then that 2008 public health notification may have come out sooner than it did if all manufacturers were fulfilling their responsibilities for reporting.
Q. All right. I'm going to move to strike everything after your first sentence where, I think, you said you were going to say a number had not been reported to FDA.
My question is: Are you going to offer an opinion that more than 29 issue reports should have been reported to FDA?
A. I might offer that opinion.
Q. And what is that opinion based on? I mean, do you have those?
A. Yes.
Q. Do you have those issue reports other than the 29 that you can tell me that you say ought to be -- ought to have been reported?
A. I can't tell you, as I sit here today. I have them available if I -- there are others if I wanted -- these are not the only 29. There are others.
Q. Okay. Where are those others? You say you have them available. I want to see

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them.
A. In my records.
Q. Did you create an Excel workbook on your MAUDE database review?
A. Well, this is separate. These are issue reports.
Q. Then I'll ask that separately.
Where -- so if I want to -- I mean, I'm entitled to know, you know, what your opinions are, and I've got your 29 issue reports that you say were not appropriately reported to FDA.
If you're going to say some number more than that 29 should have been reported to FDA, I need you to tell me, number one, what that number is, and number two, which specific issue reports those are.
A. I understand what you're asking. I think where our disconnect may be, you asked if I was going to say more than 29 should have been reported. I don't intend, as I sit here today, unless asked by counsel, to tally the total number.
I don't anticipate being asked how many should be reported -- should have been

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reported that were not of the issue reports, but if there were more than 29, these are examples.
So as I understood your question, you said are you going to say there were more than 29, and I could say there were more than 29 without giving an actual number. There were also the malfunctions.
Q. Well, and I'll get to malfunctions. But if you have an opinion that more than 29 issue reports ought to have been reported to FDA, and as I understand your testimony, you know which issue reports those are --
A. I would have to go --
Q. -- I would ask counsel that he let me know which ones they are so that we aren't ambushed at trial. I'm entitled to know --
A. I understand.
Q. -- which issue reports you think should have been reported.
MR. GOSS: Is there a question in there somewhere?
BY MS. SUTHERLAND:
Q. Does that sound fair?

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A. Yes. And if I'm asked -- if that's going to be asked --
MR. GOSS: I'm sure she'll ask me.
THE WITNESS: I can certainly do that.
BY MS. SUTHERLAND:
Q. I've got a letter drafted in my head already.
Okay. Now, those 29 examples that you pulled out are all on TVT; correct?
A. Yes.
Q. All right. Did you perform a review of the issue reports for TVT-O that were not submitted to FDA?
A. Yes, I did. I don't recall, as I sit here today, if I went through all of the 457 that Ethicon determined to be not reportable, but I certainly went through a number of them.
Q. Okay. Are you going to offer any opinion that any of the TVT-O issue reports were not appropriately submitted to FDA?
A. If asked, if asked that, yes. I might not give a specific number, but I

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would say, yes, if asked that, I would respond that there were reports that were not appropriately reported.
And the idea here is not so much a specific number, but the real underlying point is that Ethicon was down playing the adverse events that occurred using rationales for not reporting that were inappropriate, and as a result, not fulfilling its obligations that is required, both by FDA regulations and the global standard of care.
And as a result of that, then that compromises the ability of the FDA and others to see what the true safety profile, and it -- true safety profile of these products are -- or is. And the other aspect of that is this all goes to the central principles of safety and performance.
Q. You've gone way past my question now.
A. But it's all relevant. It's all relevant.
MS. SUTHERLAND: Would you read my question back, please?

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(Record read by the reporter as follows:
Are you going to offer any opinion that any of the TVT-O issue reports were not appropriately submitted to FDA?")
BY MS. SUTHERLAND:
Q. All right. And I think you told me yes, you are.
A. If asked.
Q. Now, which issue reports for TVT-O were not appropriately reported to FDA?
A. I don't have them with me today.
Q. Do you have that somewhere?
A. Yes.
Q. All right. And I'm going to ask counsel to get me those.
Do you know what number you're going to say -- or strike that.
Do you know what number you found of the TVT issue reports were not appropriately reported to FDA?
A. I don't recall the number, as I sit here today.
Q. All right. Do you know what the reports were in those issue reports that

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you're saying were not appropriately reported to FDA, meaning erosion, extrusion, pain?
A. There were a variety of different adverse events.
Q. All right. What were they?
A. Difficulty walking, pain, urinary issues, for example.
Q. Okay. Now, did you look at what was reported to FDA with respect to TVT-O's issue reports?
A. Yes.
Q. All right. Did they report reports of pain to FDA?
A. Yes, and we know that because we just went through the tabular presentation.
Q. You answered. You said yes.
Did they report reports of urinary dysfunction to FDA?
A. Yes, but that's not the issue whether they reported some. It's whether or not they reported all that should have been reported.
Q. Did they report -- I think you said that there was some reports of leg pain that

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had not been appropriately reported to FDA for TVT-O?
A. Yes.
Q. Did they report to FDA some reports of leg pain?
A. To the best of my recollection -- I would have to look back. Yes. Neuromuscular problems. I'd have to look back at exactly what the reports were.
Q. Okay. Now, how many --
A. Oh, I can do that actually.
Q. You answered my question.
A. There's difficulty walking. It's in my Exhibit 1.
Q. How many reports of leg pain for TVT-O were not appropriately reported to FDA, in your opinion, from what you reviewed?
A. I can't give you a number, as I sit here today, and I also only received a certain number of issue reports. It's my understanding, drawing from the recesses of my memory from having done this a year or two ago, I didn't receive all issue reports. The issue reports I received I went through,

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and I've given you the numbers of those which were reported as MDRs, which were not, and I can't tell you exactly, as I sit here today, how many should have been reported but that were not of the issue reports that I was given to review and had access to.
Q. And as I understand it, you also listed ten malfunctions as examples of issue reports that were not reported to FDA and should have been?
A. Yes.
Q. All right. Now, that's all for TVT; correct?
A. Yes.
Q. Do you have a number that you determined over ten that should have been reported to FDA?
A. I don't recall the specific number. Again, these are examples.
Q. Yeah. My question is: Do you have more than ten that you found that you thought should have been reported to FDA?
A. I would have to go back and tally the number.
Q. Okay. Did you look for

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malfunctions in TVT-O issue reports and determine that any should have been reported to FDA but were not?
A. To the best of my recollection as I sit here today, yes.
Q. And how many?
A. I can't give you a number without going back and checking.
Q. And do you know what type of malfunction?
A. I don't recall specifically, as I sit here today.
Q. Okay. But you have all of that information somewhere back at your office, if I'm correct?
A. Yes.
Q. Okay. Now, you also listed some late reports that -- meaning Ethicon got them and waited longer than 30 days to report them to FDA?
A. Yes.
Q. Now, as I understand it -- well, let's look on page 124. What you found specific to TVT-O were 36 late reports; is that right?

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A. Yes.
Q. All right. And as I understand it, they were late from 1 day to 19 days; is that right?
A. Yes.
Q. All right. Now, are you saying that that delay of 36 reports from 1 day to 19 days is of some sort of significance?
A. Yes. It's out of regulatory compliance.
Q. Is it --
A. It's a violation of the regulations.
Q. Is it of significance in the evaluation of the risk of TVT-O?
A. For that time frame, I would think that particular time frame didn't make a difference in terms of FDA's evaluation.
Q. I wouldn't think so either.
A. However, the requirements are set for a reason, and they are supposed to be followed, and it is a violation of their requirements, FDA requirements, not to submit within 30 days.
Q. Have you seen FDA -- well, first of

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all, did FDA take any compliance action against Ethicon for these 36 reports that were late anywhere from 1 to 19 days?
A. No. But I have seen, to answer where I think you're going with your question, FDA does --
Q. I think you answered my question.
A. -- does note in warning letters if something has not been reported or in a 483 report, but also to your question you asked me about compliance, and FDA did issue a 483 related to compliance.
Q. That was a 483 observation in 2005; right?
A. Uh-huh.
Q. And then that was responded to by Ethicon; correct?
A. To the best of my recollection, yes. If not, that would be an issue.
Q. And no further action was taken by FDA, was it?
A. To the best of my knowledge, that's correct.
Q. All right. And no -- certainly no compliance action was taken as a result of

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that 483 observation; right?
A. Yes, but understanding that when FDA performs an inspection, it's based on something very limited, and FDA has not had access to all of the information that I have had access to.
Q. Move to strike everything after "yes."
All right. The issue reports that were reviewed for TVT and TVT-O, did you actually review them?
A. Yes.
Q. Did you have help reviewing them?
A. Yes, I did.
Q. And who was that?
A. It would have been several different people over time.
Q. Who all?
A. Dr. Miriam Erberich would have been one of them, potentially Dr. Kathryn Kimmel, Wren Cherney, Andrea Friedman.
To the best of my recollection as I sit here today, those would be the staff who would have assisted me with looking at those. But any that I determined, any that

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were determined and that I've discussed as being they should have been reported but were not, that was all my evaluation.
Q. Okay. So we know for the 29 that are listed, you reviewed those.
A. Yes.
Q. And we know for the 10 malfunctions that were listed, you reviewed those.
A. Absolutely.
Q. And if I'm understanding your testimony, you reviewed others that you're not able to tell me about today that you claim should have been reported to FDA.
A. Yes. I just can't recall the specifics of those, and where people would have helped me would have been to, for example, to determine which ones were actually reported to FDA of the issue reports because we had to match that information up with the MAUDE database and verify that the ones that were not reportable we could not find MDR reports that were associated with those. So that's where they would have helped me.
Then the other aspect that I asked

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them to help me with was to go through the different issue reports and read through them and categorize them according to what the adverse reaction was. Was it difficulty walking? Was it a urinary problem? Was it erosion? What was it so that I'd have those in the categories, and then I could go through and individually review them as to what was reportable or whether it was a malfunction function and whether it was reportable or not.
Q. How were duplicates culled out?
A. The -- in two ways: We look at the -- to see if -- sometimes you'll have the same report number. It will appear more than once in your download, and we get rid of anything of that nature.
Also -- and I think I have a description in here as well, but also we would read through -- as I mentioned, we read through the event descriptions, and if it looks like everything is the same, and we can verify that everything appears to be the same in the reports, then we would not report it twice.

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Q. Okay. Did you look at how many of the reports were based on filed lawsuits?
A. I did take a look at that more recently, not so much in the number that I recall to speak about but the percentage. At various times -- and I would have to go back and look at the information to verify my memory whether it was 2012 -- I think it was 2012 to 2014 that we looked at. It could have been 2013 to 2015. I would have to go back and just double-check the years, but based on an assessment of the event description, if attorney reported was mentioned, in one of the years, it was 35 percent.
One year -- on one of the years, it was -- I looked at TVT and TVT-O, and they were both very similar. It was around 35 percent, and then one year it was 80 to 81 percent, and then in the subsequent year, it was about 50 percent.
Q. Okay. What year was it 80 to 81 percent?
A. That's what I'm trying to remember if we looked at 2012 to 2014 or 2013 to

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2015, and I have to go back and look at my records. I just can't -- I don't want to confirm without double checking my memory.
Q. Okay. There was a reference -- if you turn to your Exhibit 1 of your report, which was the MAUDE database in your report --
A. Okay.
Q. -- and on the second page, middle of the page --
A. The table.
Q. I'm sorry. First page.
A. Oh, I'm sorry.
Q. There's a reference there, fourth paragraph down, "All such MDRs were reviewed and an Excel workbook was created to record the information provided by the adverse events."
Do you see that?
A. Yes.
Q. Do you have that Excel workbook?
A. It should be in our archives.
Q. Okay.
A. We did change servers.
Q. Here we go, Hilary.

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A. It's the truth. We did. It should be there.
Q. All right. I'm going to send a request for that. You won't have any heartburn turning that over to me, would you?
MR. GOSS: Send it to me. Send the request to me.
MS. SUTHERLAND: I'll send it to you.
///
BY MS. SUTHERLAND:
Q. Did you rely on that for some of the opinions in your report?
A. Yes. We downloaded the information into the Excel workbook.
Q. Yeah. And then you used that Excel workbook when you were formulating some of your opinions; right?
A. Yes. We --
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. And some of the charts that you've had in your report?
A. Yes. Exactly.

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Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.
A. Right.
Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?
MR. GOSS: Objection. Form.
THE WITNESS: No, not without -- not without going back and reading each one.
BY MS. SUTHERLAND:
Q. And sometimes it wouldn't be in there anyways; right?
A. No, and that's why the manufacturer has responsibility to investigate.
Q. And from your review, how often did Ethicon attempt to follow up for reports?
A. My -- I'm checking my memory -- let me just double check. If you look on page 124 of the main report, I note that the majority of reports were initial reports rather than follow-up reports.
Q. Okay. Does that tell you how many

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times Ethicon tried to follow up but yet got no more information?
A. That alone does not. My own review of the information, I found a number of instances where the investigation was very limited.
Q. Can you give me an example of a particular issue report?
A. I can't without going back and looking at my records.
Q. Okay.
A. But hold on just a minute. Let me see if I can locate anything that would help to address your question.
Q. I've forgotten what my question was.
Would you read it back?
(Record read by the reporter as follows:
Can you give me an example of a particular issue report?")
BY MS. SUTHERLAND:
Q. I know you said no to that.
Are you looking for an average of attempts at follow up that might be in your report somewhere?

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A. No. That wouldn't be there, but I was going to -- I was looking to see if I might be able to give you a specific example, which I thought was your question; right?
Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.
A. Right. Then I decided to look at my report.
For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.
Q. Did you say 26 or 126?
A. 126. Sorry.
Q. Got it.
A. And, for example, it says, "Notably, it was speculation and my professional opinion for the medical reviewer to conclude that the erosion would not worsen and/or require treatment, and I reviewed no evidence of follow up by Ethicon to determine outcome of the erosion. The status was indicated as closed within approximately two months of the alert date."

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So that's an example of where they should have followed up to see if there were any consequences to really understand the safety profile of the product and feed that risk information back into the risk analysis, which should always be ongoing during the development -- during the marketing of a product, post-marketing as well as pre-marketing, to assure that there's a favorable benefit to risk ratio.

Q. As far as attempts at follow up, did you come up with any sort of average of the number of times that Ethicon attempts to follow up to get information?

A. As I sit here today, I don't recall having come up with a particular number because the point, again, is not --

Q. Well, I think you answered my question.

A. -- not the number. It's the fact that they have an obligation to follow these up to understand the safety profile of their product and report as appropriate.

Q. I'm going to move to strike everything after you didn't come up with a

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specific number.

Going back to MDR reports, are there certain requirements that have to be present in order for a reported event to be reportable to FDA?

A. Yes.

Q. Okay. And what are those?

A. It has to be a serious or life-threatening event where there is a reasonable association with the device, and as well for malfunctions, if that malfunction were to recur, that a serious or life-threatening event could result.

Q. Okay. Is there also a similar requirement for devices like there is for drugs that a reporter has to be identified, an event, a patient, and a product?

A. I'm not sure exactly what you're asking because a report from any source -- obviously, there has to be --

Q. There's got to be a reporter.

A. There's got to be a reporter.

Q. Right.

A. And information that you can follow up to determine whether or not -- to get the

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information necessary to make that determination.

Q. Yeah. My question is: In order to be a reportable event to FDA, do you, number one, have to have a product identified?

MR. GOSS: Objection. Form.

THE WITNESS: Generally speaking, I would say, yes.

BY MS. SUTHERLAND:

Q. I was going to say --

A. But -- well, no. But I'm hesitating because it's not a black and white necessarily question because you can get a report that says, "We used an Ethicon product, and we implanted this device, and the woman in whom we implanted it is continuing to have chronic infection and erosion," and they may not state what the device is.

So you have to follow that up. You need to make sure it's your product and through investigation, try and -- you have to make a due diligence effort, a valid due diligence effort, and Ethicon has its own standard operating procedures.

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They know what they must do to follow it up to determine what product it is and to find out more about the information to determine whether it's reportable, whether there's a follow-up report required, et cetera.

And the whole basis of that, again, is to always substantiate that a product is meeting the essential principles of safety and performance. If it's not Ethicon's product, and they get a report for some other manufacturer's mesh, they don't have to submit an MDR report, but they are supposed to send a letter to the FDA letting the FDA know about it so that that information doesn't get lost.

Again, all in the interest of patient safety. But, generally speaking, they need to -- you know, they could also make a report that says this -- there should always be a tendency in the global standard. There should always be a tendency in doubt, when you're in doubt, to report rather than not to report.

So if they're unable to determine

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which particular product it was, but it's fairly substantiated that it was an Ethicon product, and it was a sling, but they can't determine if it was a TVT or a TVT-O, they could still report that to the FDA and say unable to determine which sling but information confirms that it's an Ethicon sling.
Q. And did you, in fact, see where Ethicon did that very thing?
A. I don't recall a specific example of that, as I sit here today.
Q. Are you saying it didn't happen, or you just don't recall?
MR. GOSS: Objection. Form.
THE WITNESS: No. I just don't recall, as I sit here today.
BY MS. SUTHERLAND:
Q. All right. Did you look at the reported events to see whether or not Ethicon took even a more conservative approach and reported something that you wouldn't have reported?
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:

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Q. Did you perform that review?
A. As you've asked the question, as I understand it, I didn't perform that review.
Q. Okay.
A. As I mentioned, there should always be a tendency, if there's any question, to report rather than not to report.
Q. Okay. Move to strike everything after "I did not perform that review."
Is there a requirement for some sort of identifier of a patient in order for an adverse event to be reportable, meaning the gender of the patient, the age, something like that?
A. The age, no. The gender, not necessarily. If it's a device that can be used in both sexes, you provide -- again, that's why you investigate. You try and obtain as much information as necessary, and then you make an appropriate judgment as to whether or not it needs to be reported.
Q. All right. Let's switch gears again, and I'm going to walk you through some particular aspects of your report that we haven't already covered, part of which

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I'm going to start with the Global Harmonization Task Force issues.
A. Okay.
Q. Now, am I correct that the Global Harmonization Task Force was sort of formed in 1992?
A. Yes.
Q. All right. And as I understand it, there were members from different countries, approximately five --
A. Yes.
Q. -- for sort of the task force.
A. Countries or regions.
Q. All right. And would that be the European Union?
A. Yes.
Q. The U.S.?
A. Yes.
Q. Canada?
A. Yes.
Q. Japan?
A. Yes.
Q. And France?
A. Oh, I think it was Australia.
Q. Oh, they met -- yeah, I think

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you're right. Australia.
Was the purpose of the GHTF to come up with some documents that harmonized regulatory processes across the countries?
A. Yes. To provide a global model --
Q. All right.
A. -- for development of medical devices with the intent of patient safety and being able to bring important new technologies to the market in a safe, cost effective, efficient manner.
Q. And in that effort to reach that goal, am I correct that certain guidances were promulgated by the GHTF?
A. Yes, that's correct.
Q. All right. Was the intent then that those guidances would then be adopted by the regulatory agencies of those different countries or regions?
A. Yes. And even beyond those countries and regions but would even be more global and other countries that didn't have as well -- the countries and regions that were involved had more established regulatory framework for medical devices,

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and so for countries and regions that didn't have as well developed regulatory framework, this would also -- the GHTF guidance documents would also help those countries to be able to have a framework for development of safe and effective medical devices.

Q. And all of this was for the regulatory processes in the different countries to be harmonized so that, for instance, a manufacturer in one country knew what was required for clearance in another country across the globe.

A. It was more than that. It certainly was for that purpose, but it was also to establish the standards for testing, for labeling, the guidances for risk management, quality system for manufacturers because the Global Harmonization Task Force was a partnership between the industry and regulators so that there was equal representation across industry and regulators for GHTF for its approximately 20-year history.

Q. Now, study groups were created under the umbrella of the GHTF; correct?

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A. That's correct.

Q. And there were five of them?

A. That's correct.

Q. And those leaders of those study groups were all regulators, weren't they?

A. I don't know specifically if the leaders were all regulators. The study groups were compromised of both regulators and -- both regulators and industry representatives.

Q. All right. I'm going to hand you what I've marked as Exhibit Number 12.

(Exhibit Number 12 was marked for identification.)

BY MS. SUTHERLAND:

Q. This is a printout of AdvaMed's 40th anniversary discussing the GHTF. Now, have you ever seen this document before?

A. I don't recall, as I sit here today, having seen this particular one.

Q. All right. What is AdvaMed?

A. It's an industry organization that represents medical device companies.

Q. Okay. Is it the largest medical

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device industry group in the United States?

A. I would say, yes.

Q. All right.

A. That's my understanding.

Q. Now, under this first section there, Global Harmonization Task Force of 1992, it sets out sort of what we've already talked about that in September 1992, senior regulate officials and industry reps from those different areas met in France; correct?

A. Right.

Q. And that was for the purpose of exploring "the formation of a global partnership chartered to harmonize medical device regulatory practices worldwide"; is that right?

A. That's what this says, yes.

Q. Is that not right?

A. No. I said that was right, but, I think, it also provides documentation for how to develop a medical device to guide manufacturers and how the appropriate methods -- the appropriate types of testing, labeling requirements, risk assessment,

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quality system, it sets out the standards for medical device companies to follow in being able to bring safe, effective, quality products to market.

Q. Now, those guidances were based on regulations already in place in the different countries that were members of GHTF, weren't they?

A. They utilized those, yes. But, again, it's a representation of medical device industry, AdvaMed participated. If I recall correctly, AdvaMed was on the steering committee, and AdvaMed participated, representatives from companies that were part of AdvaMed participated, and then the regulators.

Q. Now, the third paragraph in there said that "The mission of GHTF was to encourage the convergence in regulatory practices related to ensuring the safety, effectiveness, and quality of medical devices."

Do you agree with that statement?

A. Yes, as well as the rest, which is promoting technological innovation which has

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to do with companies --
Q. Right.
A. -- and facilitating international trade.
Q. Correct. And then it goes on and says, "This important task was accomplished through the development and dissemination of harmonized guidance documents on regulatory practices."
Do you agree with that statement?
A. Yes, but it's more than regulatory practices because there are documents that talk about clinical evaluation, what clinical evidence means, all of the same kind of -- it's not just for regulators.
This information is intended to be used by companies developing products in order to take the appropriate steps and have a model to follow to produce safe and effective and high-quality products, quality product, to bring to the market in their various regions or countries.
Q. It goes on to say, "These critical documents" -- meaning these guidances -- "which were developed by the five different

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study groups were then to be implemented by member national regulatory authorities to further the goal of harmonization."
Now, was that -- is that your understanding of what was to be accomplished through the GHTF?
A. Yes.
Q. Okay.
A. Yes.
Q. Which GHTF guidances were adopted by FDA?
A. There are -- there are a number of those like, for example, the auditing one. FDA is currently using a GHTF auditing guidance in cooperation with, I believe, it's Japan and maybe Canada -- I'd have to check back to refresh my memory -- to look at an auditing model to audit medical device companies so that they don't have to be audited by multiple countries and that by working together through GHTF, the GHTF model for auditing, that they all accept that whatever the audit is, that they will accept the -- it's a pilot program currently.

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Q. And that pilot program that you're talking about, is that set out in some sort of FDA document?
A. Yes. It's on the -- you can find it on the FDA website.
Q. All right. Other than that pilot program that you're talking about on auditing, did FDA adopt any other guidance put out by GHTF?
A. If you'll -- Tim Ulatowski, who is your expert in these cases, actually, back around --
Q. Well, you note something from him from 2009 in your report.
A. I said they were becoming -- that companies should be aware of them, that they were becoming the standard. And --
Q. And my question is a little bit different.
MR. GOSS: Wait, wait, wait, wait. Slow down a little bit.
BY MS. SUTHERLAND:
Q. My question was specifically on whether you can tell me which, if any, guidance put out by GHTF has been adopted by

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FDA.
A. I would have to check the status of it. I know that there was also a pilot program where the FDA was encouraging the use of the STED document for submission of medical device applications. I would have to check the status of that, at this point in time.
Many of the GHTF documents are very reflective already of the FDA regulations because obviously FDA was a major participant.
Q. Now, is this the pilot program on the STED that you're talking about?
Let me mark that as 13.
(Exhibit Number 13 was marked for identification.)
THE WITNESS: Yes.
BY MS. SUTHERLAND:
Q. Okay. Now, I'm not aware of that actually being implemented past 2005. Are you?
A. Not without checking, I don't recall.
Q. All right. So now other than the

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two pilot programs that you've mentioned to me, are you aware of any guidance from GHTF that FDA has adopted?
A. As I sit here today, I don't recall without going back and looking at all of them --
Q. Okay.
A. -- and checking. What I can tell you in answer to your question is that the reason for -- I was able to find some further documentation. The reason for disbanding GHTF and transitioning GHTF's work to IMDRF was specifically for that purpose. That incorporation of these guidance documents into the regulatory framework to the regulations had been slower than had been hoped and so --
Q. In fact, not at all; right?
A. Well, in some places, I don't think that's true. They are in the U.S.
Q. In the U.S., not at all; right?
A. In the U.S., but in other places, they were being incorporated, but the incorporation was slower than anticipated, and so the regulators decided that they

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could make that happen after the 20 years of GHTF and with the global framework that had been developed, that now if the regulators were to take the ball, if you will, that they could work more effectively to get the GHTF guidance documents and any new documents that IMDRF would develop incorporated into the regulations of their respective areas.
Q. All right. And IMDRF doesn't have industry representatives right?
A. No. It's all regulators.
Q. All regulators. Okay.
MS. SUTHERLAND: How much time do we have?
THE VIDEOGRAPHER: About -- you're at 5 hours 24 minutes.
MS. SUTHERLAND: Let's keep going.
BY MS. SUTHERLAND:
Q. Flip over to page 42.
A. Of my report?
Q. Of your report, yes, ma'am.
A. 42?
Q. Yes, ma'am.

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And I just had a quick question. You note there about the Medscand payments of 400,000 --
A. Yes.
Q. -- and that -- are you offering an opinion that that financial information should have been disclosed in the TVT 510(k)?
A. Yes.
Q. All right. And am I correct, though, that the regulation requiring that type of disclosure actually wasn't finalized until after the submission of the TVT 510(k)?
A. That is correct.
Q. All right. Let's move on to page 54. And as I review your report, at least for this specific one, I understood you to be saying that there were two cytotoxicity tests that should have been provided to FDA?
A. Yes.
Q. All right. Now --
A. Or should have -- and should have been also followed up further to understand

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why they were getting positive cytotoxicity tests.
Q. Okay. I got you.
But what I'm going for here is what are you going to tell a jury that Ethicon should have given to FDA but didn't, and I know you and I have talked about the MDRs. We've now talked about these two cytotoxicity tests.
A. Right.
Q. Now, is there other specific documentation that you're going to say Ethicon should have given to FDA but didn't with respect to the TVT-O?
MR. GOSS: Objection. Form.
THE WITNESS: For example, the issues with fraying and particle loss of the mesh, the mechanically cut mesh, the roping, the curling.
BY MS. SUTHERLAND:
Q. Yeah. I'm asking about can you name for me a specific document that you're talking about that you say Ethicon should have give to FDA but didn't?
A. Well, there are a number of

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documents related to the fraying, the particle loss.
Q. Can you tell -- I mean, I need to know if you're going to say, "Ethicon should have given this document to FDA," I want to know what this document is.
A. Well, for example, if I'm recalling correctly, Gene Kammerer's, the engineer, lead engineer, Gene Kammerer -- there's a -- I believe it's a PowerPoint presentation where they're actually pictures of the mesh and the particle loss and how the structure is lost, the mesh structure is lost, and the word "degradation" was used separate from degradation once implanted, but degradation of the structure of the mesh and the particle loss and the fact that there was no testing to determine whether or not those particles might have any impact for safety and effectiveness.
The narrowing -- the narrowing and the roping and the curling of the mesh, the fact that that was considered, and it's been testified to by Ethicon employees that that was a product defect.

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Q. Okay. Now, you told me about a PowerPoint --
A. I believe it was a PowerPoint.
Q. -- by Mr. Kammerer.
A. Yes.
Q. All right. What other document are you going to say should have been given to FDA but wasn't?
A. At that point in time --
Q. And what point in time are we talking about?
A. Submission of 510(k).
Q. Okay.
A. Some of the documents I have referenced, I don't have years indicated in my reference. So without checking back the document, I can't say whether it had the information available at the time of submission or not, but I do know, for example, that by November, 2003, that they had -- Ethicon had at least had received a total of 58 complaints of fraying, and they also had information from their preceptors about denaturing and linting being a concern, leaving particles in patients.

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Q. Those 58 reports of fraying, were they reported to FDA's MDRs?
A. To the best of my recollection, there may have been some but not all. I'd have to go back and check my records. That's to the best of my recollection.
Q. Okay.
A. And let's see -- yes. I know for sure that in the discussion of malfunctions in the back of my report. Definitely there -- there, for example, eight reports of the mesh fraying, unraveling, and on fragments falling off, the tape becoming particles. So there were definitely reports that were not submitted to FDA.
Q. Okay. But there were actually some reports of fraying that were reported to FDA by Ethicon; right?
A. I'd have to go back and double check.
Q. You don't know that sitting here today?
A. There are many MDR reports. To the best of my recollection as I sit here today, there were some, but I'd have to just verify

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my memory.
Q. Okay.
A. And that's very important because that goes not only to determining safety and effectiveness, that's an important consideration for FDA's determination of substantial equivalence, and that information was known to Ethicon and not provided to the FDA.
Q. Move to strike everything after your first clause where, I think, you said that you thought some were reported to FDA, but you'd have to confirm.
Let me get you to move to page 107 of your report.
A. Okay.
Q. And if we're flipping through there, by my count, you pull out five pieces of promotional material on pages 107 to 114. Is that right?
A. I'll double check. Yes.
Q. All right. Now, are those five pieces of promotional materials what you're relying on to support your opinion number 4?
A. Yes.

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Q. Now, let's go back and look at -- on page 107, the first piece that you have there.
A. Okay.
Q. All right. First of all, that one's entitled "Only Gynecare TVT Has Long-Term Results You Can See -- blah, blah, blah -- "and Believe."
A. Right.
Q. All right. Now, do you have any information that the implanter in the Jennifer Ramirez case, Dr. Reyes, saw that piece?
MR. GOSS: Objection. Form.
MS. VERBEEK: Same objection.
THE WITNESS: I don't recall that he testified about this --
BY MS. SUTHERLAND:
Q. Okay.
A. -- as I sit here today.
Q. All right. Have you done any kind of survey of surgeons to determine what their perception is of this particular piece, number 1, on your report, page 107?
A. No. My evaluation was based on

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what the requirements are for promotional labeling.
Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?
A. That's correct.
Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?
A. I'm not opining that. What I'm opining is that there is -- any time there is a financial arrangement that could impact one's assessment of data and particularly where positive data is required in order for a payment to be made, there is the potential for bias, and that information should be disclosed so that the reader of -- in this case, the promotional labeling, understands that there was financial incentive for the authors of that data.
I'm not saying that they did. I'm saying that presents a potential for bias, and that's the reason it should be

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disclosed.
Q. And then move to page 110 of your report, and there's your second marketing piece.
A. Yes.
Q. All right. Now, do you have any information that Dr. Reyes saw this particular marketing piece?
MS. VERBEEK: Object to form.
MR. GOSS: Objection. Form.
THE WITNESS: To the best of my recollection as I sit here today, I don't recall that he testified as to having seen this particular piece.
BY MS. SUTHERLAND:
Q. All right. Now, did you perform any kind of survey to determine how physicians perceived this particular marketing piece?
MR. GOSS: Objection. Form.
MS. VERBEEK: Objection. Form.
THE WITNESS: My assessment was based on the requirements for what is supposed to be in promotional labeling. I did not perform a survey.

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BY MS. SUTHERLAND:
Q. And with respect to -- you note, again, the financial conflict of Professor Ulmsten and Nilsson; right?
A. Yes.
Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph?
A. Yes, I do.
Q. Okay. Now, are you opining that Professor de Leval manipulated his data to make it inaccurate?
A. No. I'm, again, opining that there's a potential for bias and because of that potential for bias, it is the standard, it's a requirement from a regulatory standpoint at this point in time, in fact, by the time of the TVT-O but no clinical data was included in the special 510(k) for TVT-O.
It's a regulatory requirement, but it's also the standard of -- the standard for publications that that type of information be disclosed.
Q. Okay. Move to strike everything

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after "no."
If you turn to page 112 of your report, and that gets us to your third marketing piece?
A. Yes.
Q. And this one is dated 2010?
A. Yes.
Q. All right. Now, do you have any information that Dr. Reyes saw this marketing piece?
MR. GOSS: Objection. Form.
THE WITNESS: I don't recall.
MS. VERBEEK: Objection. Form.
THE WITNESS: I don't recall having seen testimony that as regards his having seen this piece.
BY MS. SUTHERLAND:
Q. Okay. Did you perform any kind of survey to determine physicians perceptions of this particular marketing piece on page 112?
MR. GOSS: Objection. Form.
MS. VERBEEK: Object to form.
THE WITNESS: With the same comment as I made for the prior two, no,

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I did not.
BY MS. SUTHERLAND:
Q. Okay. Turn to page 114. And up at the top, we have your fourth marketing piece.
A. Yes.
Q. And, again, do you have any information that Dr. Reyes saw this particular marketing piece?
MS. VERBEEK: Object to form.
THE WITNESS: I do not recall his having testified that he had seen this, as I sit here today.
BY MS. SUTHERLAND:
Q. Okay. Did you perform any kind of survey to determine physicians perception of this particular piece?
MR. GOSS: Objection. Form.
MS. VERBEEK: Object to form.
THE WITNESS: My assessment and my opinion is based on a review of -- based on a review of the piece as regards the requirement for promotional labeling must meet, just as for the other pieces, and I did not perform a

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survey.
BY MS. SUTHERLAND:
Q. All right. And for the last piece on page 5, did you perform any kind of survey to determine physicians perception of that fifth marketing piece?
MS. VERBEEK: Object to form.
THE WITNESS: With the same comments as for the prior promotional labeling pieces, no.
BY MS. SUTHERLAND:
Q. All right. And do you have any information that Dr. Reyes saw this particular piece?
A. I don't recall any specific information in his testimony as regards to this piece, as I sit here today.
Q. Under your opinion there, the second sentence you note, "Labelling can be deemed by FDA to be misleading and in violation of FDA requirements if it proves deceptive to the customer by creating or leading to a false impression in the mind of the reader."
Did I read that correctly?

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A. Yes, you did.
Q. All right. Now, number one, has FDA ever issued any kind of documentation for these five pieces saying that they were misleading or in violation of any FDA requirement?
A. Not that I've seen, but they were not just submitted to FDA, as far as I know. So they weren't provided to FDA for comment.
Q. Move to strike everything after "Not that I've seen."
And with respect to determining if the piece proved deceptive to the customer by creating or leading to a false impression in the mind of the reader, would the reader be intended to be obviously a physician; correct?
A. Yes. For these pieces, yes.
Q. All right. Did you talk to any physician who actually saw any of these pieces?
A. No, I did not. And I've given my rationale for each of these pieces as to why it was false and misleading.
Q. And we already know that you didn't

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do any kind of survey to determine if any physician got a false impression in their mind after reading any of these five pieces; correct?

MR. GOSS: Objection. Form.

THE WITNESS: Based on my experience --

BY MS. SUTHERLAND:

Q. Is that a yes or a no?

A. I can't give you just a yes or no.

Q. Well, you didn't do a survey; right?

A. I have, based on years of experience and knowledge and reviewing, a number of warning letters about what should be in promotional labeling and what should not as well as correspondence between companies who have submitted labeling of this type and FDA correspondence and based on what the requirements are for what's supposed to be included, I made my assessment based on that and not a survey because there's a certain standard that must be met, and I made my assessment, and I've given the rationale for each piece as to

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where it was false and misleading.

And I made my assessment based on what the requirements are for this type of labeling.

Q. All right. So in order to reach this opinion -- essentially, we have your opinion that under the FDA regs, it would create or lead to a false impression in the mind of a physician; correct?

A. My opinion based on many years of experience.

Q. What we don't have is you even talking to a single physician to confirm your opinion; correct?

MR. GOSS: Objection. Form.

MS. VERBEEK: Object to form.

THE WITNESS: I have not talked to a single physician. I based it on the requirements for this type of labeling and given the rationale for it, for my opinions.

BY MS. SUTHERLAND:

Q. Do you intend to opine that Prolene mesh is carcinogenic?

A. I don't intend to opine that it's

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carcinogenic. If I'm asked about that, I would opine that there have been cases now that have been reported where polypropylene as well as other polyester meshes and TVTs have been found in association with tumors and that the authors of those reports have not concluded that the mesh was the cause of the tumor but that it may have been a contributing factor.

Q. And are those case reports, the, I think, four or five that are set out in your report?

A. Yes.

Q. Are there any other pieces of medical literature that you've looked at addressing whether or not mesh is carcinogenic?

MR. GOSS: Objection. Form.

THE WITNESS: There is, as discussed in my report, in one of the points I said should have been in the warnings that there were rat sarcomas that were identified in the material safety data sheet with implantation.

BY MS. SUTHERLAND:

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Q. I should have specified. I'm asking about medical literature. Did you look at any other medical literature that addresses an issue of whether or not mesh is associated with cancer other than what you've got in your report?

A. I certainly have -- I can't give you a specific -- I know I have looked at solid state tumors and mesh and various -- I've looked into that. I can't give you a specific document. I have done some research on it. I can't give you a specific document that I recall, as I sit here today.

Q. All right.

A. Those case reports are important because of the information that they present, and it needs to be considered and for long-term implants, testing for -- and that goes into the testing for long-term inflammation, long-term infection.

These are -- this is one of the reasons, for example, for doing further testing, for having a registry. Without having the appropriate follow up of these patients, making such an association is

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difficult. It cannot be done actually.
Q. All right. I'm going to move to strike everything after your first clause.
Would you agree with me that TVT-O -- the mesh in TVT-O is Prolene mesh.
A. Yes.
Q. All right. And would you agree with me that Prolene mesh has been used in the body since the 1970s?
MR. GOSS: Objection. Form.
BY MS. SUTHERLAND:
Q. You know it was a preeminent device; right?
THE WITNESS: Yes, I do.
MR. GOSS: Objection. Form.
THE WITNESS: Yes, I agree with that, but there's more to be considered than just that fact.
BY MS. SUTHERLAND:
Q. Okay. Well, my question is do you know, or do you not know that Prolene mesh has been used in the body since the 1970s?
MR. GOSS: Objection. Form.
THE WITNESS: Yes, I know that.
BY MS. SUTHERLAND:

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Q. Okay. Now, in the in 40 some-odd years that Prolene mesh has been used in the body, is there a single case report where a doctor attributed cancer to Prolene mesh?
MR. GOSS: Objection. Form.
THE WITNESS: Well, the TVT is Prolene mesh.
BY MS. SUTHERLAND:
Q. Well, that doctor didn't attribute the issue to TVT, did he?
A. In one case, the authors concluded that the bowel cancer in both cases is unlikely to be caused by the mesh, but chronic irritation by the mesh may be a contributing factor and further cautioned -- this is the key point -- that it is important to keep in mind that mesh surgery, especially for prolapse procedures, has been used for a relatively short duration of time, and there may still be unknown long-term complications associated with their usage.
Q. Does Ms. Reyes have cancer? I'm sorry. Ms. Ramirez.
MR. GOSS: Objection. Form.

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THE WITNESS: If she does, I have not seen any information with regard to that.
BY MS. SUTHERLAND:
Q. Okay. All right.
A. I hope she doesn't.
Q. I hope she doesn't either.
MS. SUTHERLAND: Let's go off for a few minutes. I think I've got maybe ten minutes. Let me make sure I've covered everything.
MR. GOSS: Are you going to leave your co-defendant any time in the six hours?
MS. SUTHERLAND: I didn't know I needed to.
MS. VERBEEK: You probably don't. You've worn me out.
MS. SUTHERLAND: I've worn myself out.
THE VIDEOGRAPHER: Going off?
MS. SUTHERLAND: Yes.
THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately

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4:37 p.m.
(Recess taken from 4:37 p.m. to 4:43 p.m.)
THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 4:43 p.m.
BY MS. SUTHERLAND:
Q. Doctor, let me get you to turn back to page 59 of your report, if I could, and this actually sets out your first opinion in your report; right?
A. Yes.
Q. Now, as I understand it, you've got an opinion that Ethicon failed to conduct appropriate pre-market testing of the TVT-O?
A. That's correct.
Q. All right. Are you intending to opine as to the specific protocol of trials that Ethicon should have done pre-market that it did not do for TVT-O?
MR. GOSS: Objection. Form.
THE WITNESS: Let me make two points. One is that they didn't do the appropriate testing pre-market but also as new information was obtained and, for

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example, marketing of the laser-cut mesh, post-marketing, they didn't -- they didn't do appropriate testing either.

If I were to be asked what type of study should have been done, I will respond to that. I don't know if I'm going to be asked that kind of question. I could certainly opine about what types of testing should have been done, but the testing was inadequate.

BY MS. SUTHERLAND:

Q. Okay. Let me ask it this way: Do you intend to opine that Ethicon should have done clinical testing of TVT-O before marketing the TVT-O?

A. Yes.

Q. All right. Are you intending to opine as to a specific number of women that should have been enrolled in a clinical trial pre-market?

A. I don't intend to offer a specific number of women because, as you and I have discussed before, in order to arrive at a specific number of women -- I could give

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potentially a range that would have been appropriate, but in order to arrive at a specific number, one has to design the study.

What the endpoints are. If it's a comparative study, what the differences one expects to see or no differences between a -- one product and another depending on what type of trial it is. Then one then needs to give that information to a statistician who does his calculations to let you know how many patients you need to include considering the possibility for dropouts in order to be able to end up with the right number of patients to be able to answer the questions you're intending to ask by your protocol.

Q. One is the loneliest number.

A. One meaning a person.

Q. So as you sit here today, have you, in fact, designed a protocol that you intend to opine about with respect to TVT-O -- strike that.

As you sit here today, have you put together a protocol that you intend to opine

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about during this particular trial?

A. No. As I sit here today, no.

MS. SUTHERLAND: All right. I'm going to hand it to co-counsel for any questions and maybe save three minutes for my follow-up questions.

MS. VERBEEK: I'll reserve.

MS. SUTHERLAND: How much time do we have?

THE VIDEOGRAPHER: Nine minutes.

MS. SUTHERLAND: All right. Let's go off. We'll switch.

THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately 4:47 p.m.

(Recess taken from 4:47 p.m. to 5:06 p.m.)

THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 5:06 p.m.

EXAMINATION

BY MR. GOSS:

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Q. Good almost evening, Dr. Pence.

A. Good evening.

Q. For the record, we met before. I'm Tim Goss. You know I represent Jennifer Ramirez.

A. Yes.

Q. And I retain -- my firm retained you as an expert for her case.

A. Yes.

Q. And we are in Newport Beach, California, and you are giving your deposition in that case today; is that right?

A. Yes, I am.

Q. And you've given your deposition before?

A. I have.

Q. You understand that this case may go to trial in San Antonio, Texas?

A. Yes, I do.

Q. And do you understand that your testimony today is as if you are sitting in that courtroom talking to that jury?

A. Yes, I do.

Q. Okay. And you've testified before

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juries before?
A. Yes, I have.
Q. Okay. Where do you currently reside?
A. Newport Beach, California.
Q. And where did you reside before that?
A. Newberry Park, California.
Q. You just recently moved to Newport?
A. That's correct.
Q. Why did you move to Newport?
A. My son and his family, including my three grandchildren, live in Newport Beach.
Q. Where did you grow up?
A. I grew up in the south in Texas.
Q. Where in Texas?
A. I of New Braunfels and Wichita Falls, Texas.
Q. So you're a little familiar with San Antonio, Texas?
A. Yes, I am.
Q. Okay. Let me mark your CV. I'm going to hand you what's been marked as Pence Exhibit 14.
A. Thank you.

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(Exhibit Number 14 was marked for identification.)
BY MS. SUTHERLAND:
Q. And is that your personal CV?
A. Yes, it is.
Q. Okay. I'm going to walk through a little bit of this, and I'm not going to spend a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay?
Where did you go to college?
A. I did my undergraduate work at Louisiana Tech, Louisiana Polytechnic University, usually known as Louisiana Tech.
Q. Were you born in Louisiana?
A. No. I was actually born in Georgia.
Q. Okay. Did you get a degree at Louisiana Polytech?
A. Yes, I did.
Q. And what did you get that degree in?
A. My major was microbiology with minors in chemistry and zoology.

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Q. And what type of degree was your major?
A. Bachelor of science.
Q. Okay. Why did you get it in science?
A. From the time I was a little girl, as far back as I can remember, I was always interested in the medical field and in science and doing something to contribute and help people to feel better, to be better, better quality of life.
Q. After you obtained your degree, your bachelor of science in microbiology, did you do further studies?
A. Eventually I did, yes.
Q. And did you get another degree?
A. Yes, I did.
Q. What did you get?
A. A got a doctor of philosophy or a Ph.D. degree with a major in toxicology, a minor in pharmacology.
Q. Where was that?
A. That was at Indiana University Medical School.
Q. And that's why we call you doctor.

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A. Yes.
Q. You're not a medical doctor?
A. No, I'm not.
Q. Why don't you explain to the jury what toxicology is?
A. Toxicology is the study of poisons in the context of medical device and pharmaceutical product development. It focuses on the study of the potential adverse effects of medical devices or pharmaceutical type drugs on the human body or on animals predicting what may happen in humans.
Q. And you got your Ph.D. in toxicology?
A. Yes, I did.
Q. Tell the jury a little bit about what getting your Ph.D. entails.
A. It requires, of course, a lot of didactic training, a large amount of coursework, and then for a Ph.D., it requires independent research and presenting that research to a committee, writing up your results, and getting those -- submitting those results to the university,

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being examined on those results by your committee, and they're assuring that you meet the qualifications to receive your receive your Ph.D. degree.
Q. You got a minor in pharmacology. Explain to us what pharmacology is.
A. Pharmacology -- toxicology is a subset of pharmacology. Pharmacology is the study of both the adverse effects as well as the -- more principally the effects of drugs that are positive, how -- the beneficial effects of drugs, how they act on the body, how the body responds to them.
Q. So the study of toxicology and pharmacology would include the study of the benefits and risks of drugs?
A. That's correct.
Q. Okay. How long does it generally take for someone to get a Ph.D. in toxicology?
A. It generally takes four to five years after -- once one enters the program. In my case, it took, if I recall correctly, a little over seven years because I was also working full-time for a large part of that

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time and raising a couple of children.
Q. Right. Are you currently employed?
A. Yes, I am.
Q. And how are you currently employed?
A. I am employed by Symbion Research International.
Q. Okay. What is Symbion?
A. Symbion is a consulting company and contract research organization. We work with companies like medical device companies, pharmaceutical companies, companies developing biological therapeutics to assist them with understanding what the requirements are, what they need to do to bring their products to the market, assuming that the products turn out to be safe and effective through all the appropriate testing, and we work with them to help get their products through the FDA process prior to marketing and post-marketing.
Q. That's how you're currently employed. Now I'm going to back you way up. When you got out of school, where did you go to work?
A. My first job after school was Eli

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Lilly and Company.
Q. Is Eli Lilly and Company similar to Johnson & Johnson and Ethicon?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes. It's a large pharmaceutical company.
BY MR. GOSS:
Q. Okay. And what did you do for Eli Lilly?
A. I started out working in a basic research laboratory developing various types of assays and doing animal research in the -- in immunology.
Q. What year was that?
A. 1970.
Q. 1970?
A. 1970.
Q. So for almost 40 years, have you been either working with the industry or for a pharmaceutical company?
A. This is my 47th year of work, I think, when I calculated it recently.
Q. And has that all been encompassed with either being employed by pharmaceutical companies or advising pharmaceutical

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companies or manufacturers?
A. Yes. And one part of that period, there was a three-year period where I was still employed by Eli Lilly and Company but worked in developing cosmetics. There are correlations between -- cosmetics are also regulated by the FDA.
Q. I saw you also worked for Serono. Is that how you say it?
A. Yes, it is.
Q. What kind of company is that?
A. Serono Laboratories is also a pharmaceutical company.
Q. You worked for Triton?
A. Yes, I did.
Q. What is Triton?
A. Triton was a pharmaceutical company, a biotechnology company. It was, at the time, a wholly owned subsidiary of Shell Oil Company, and ultimately Shell -- it was acquired by Berlex.
Q. And you worked for Amgen?
A. Yes, I did.
Q. What's Amgen?
A. Amgen is probably the major

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independent biotechnology company in the country.
Q. After Amgen, then you went to work with Symbion?
A. Yes. For a three-year period prior to incorporating at Symbion, I operated as an independent consultant and then incorporated Symbion Research International, founded the company in 1995.
Q. Okay. I'm going to ask you just an overview of some things that you did for these companies while you were working for them.
Did you design clinical trials?
A. I did. Many.
Q. What's a clinical trial?
A. A clinical trial is a research study in humans, and a clinical trial specifically is one where patients are randomly -- are assigned prospectively, I should say, to one or more treatments.
Q. Did you do laboratory work?
A. Yes.
Q. Did you deal with clinical affairs?
A. Yes.

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Q. What's clinical affairs?
A. Clinical affairs is the group within companies that deals with the human phase of testing of products.
Q. Did you -- were you responsible for collecting data?
A. Yes, I was. Many times.
Q. Okay. What types of data?
A. A variety of types of data. All the types of data that are collected in clinical -- in a clinical trial or any type of clinical study where one is looking -- is administering one or more types of treatment to a patient, different patients, human subjects, and evaluating the outcome, both safety and effectiveness data.
So it would include data to determine whether or not the product is working for its intended use. It would include adverse reaction information and clinical laboratory information, a whole scope of information including patient demographics.
Q. Part of what you've done in this case is look at the product development for

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the TVT-O; is that right?
MS. SUTHERLAND: Objection.
THE WITNESS: That is correct.
BY MR. GOSS:
Q. Did you have any experience in product development in your early employment?
A. Yes. My whole career has been involved in one aspect or another of product development. In particular at Triton, I was a project manager where I was responsible for oversight of product development from basic research all the way through in preparation for market launch.
BY MR. GOSS:
Q. At any of these companies, did you hold responsibility for making sure the companies were complying with industry standards?
MS. SUTHERLAND: Objection.
THE WITNESS: Always, yes. Especially once we got into the regulatory and clinical development area, and that was particularly in 1997. I'm sorry. 1977.

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BY MR. GOSS:
Q. What was that in connection with?
A. I transferred at Eli Lilly and Company into the clinical and regulatory area.
Q. And so you were in the clinical and regulatory area at Eli Lilly?
A. Yes. As a medical information -- and my title was medical information administrator.
Q. What did that entail?
A. A variety of -- a variety of roles, if you will. I was responsible for working pre-marketing and with data pre-marketing and post-marketing. In some aspects, I actually monitored clinical trials, meaning that I would go out to the investigative sites where the studies were being conducted to make sure that the physicians and the physician staff were conducting the study according to the protocol, which is the document that describes how a study should be conducted and according to regulations as well.
And I was responsible for

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collect -- to evaluating data and tabulating data, both pre-marketing and post-marketing, in particular adverse event data.

For example, I worked on the very first recombinant DNA product ever to be marketed, which was human insulin, and one of my roles at Eli Lilly was involvement in the collection of data once the product went on the market, safety data in particular, to present to FDA.

There are certain requirements, regularly reporting of adverse event data post-marketing of a new drug such as that.

Q. What experience have you obtained over your 40-something years in the industry with respect to labeling of product, drugs, and devices?

A. Again, a variety of experience. In terms of clinical trials, there's a document called the Investigator's Brochure. It's also been termed proto labeling. It's basically for products prior to their marketing, it is the document that provides the same type of information that's included in a package insert for a drug or in the

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context of a medical device and instructions for use or directions for use, which we refer to as an IFU or a DFU.

The purpose of that is to give the physician the information that he or she needs to be able to use the product safely and effectively based on the known information.

So I've prepared a number of those Investigator's Brochures over my career, written them in their entirety, and then I've also been involved in the review and/or development of IFUs, for example, for medical devices.

Q. Have you been involved in safety surveillance?

A. Yes.

Q. What is safety surveillance?

A. Safety surveillance -- are you talking about post-marketing safety surveillance in particular?

Q. Sure.

A. It is evaluating the safety data that is available once a product goes on the market through post-marketing clinical

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trials, through reports of complaints, adverse events that are reported to the company once the product is on the market as well as in reviewing the medical and scientific literature for reports of adverse events.

So I've done that post-marketing, and on the pre-marketing side in terms of clinical trials, as I may have mentioned earlier, constantly evaluating adverse events that are being -- that are occurring during clinical trials, assessing those, very serious ones that are unexpected that meet certain criteria, reporting those to the FDA in a required time frame and submitting them to doctors as well.

Q. Have you consulted with companies with respect to regulatory matters?

A. Yes, frequently.

Q. Is that mostly with Symbion?

A. It's not only with Symbion. Prior to that, while my roles were in clinical and project management, within companies such as Eli Lilly, Amgen, work is done -- all the companies where I've worked, work is done as

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a part of a project team, and I've been involved in preparing many submissions to the FDA, presenting -- prior to being at Symbion, starting at Symbion, I've presented to FDA on many occasions the proposed plan for the studies that we were going to conduct.

I've been involved in an advisory committee meeting as well preparing the information for that post-marketing.

Q. How many pharmaceutical and/or device companies have you advised over your 40-plus years in the industry?

A. Over 80.

Q. Involving how many drugs or devices?

A. Over 90.

Q. Do you have experience with Class 1, Class 2, and Class 3 medical devices?

A. Yes, I do.

Q. How did you obtain that experience?

A. The majority of that experience was obtained after I started my own consulting practice beginning in 1992 and then through

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Symbion as well.
Q. Have you advised manufacturers with respect to the adequacy of their medical device labeling?
A. Yes, I have.
Q. Have you advised manufacturers with respect to whether or not they should perform clinical studies?
A. Yes, I have.
Q. And what types of studies to perform?
A. Absolutely. I've designed the clinical studies on many occasions.
Q. Did you, during this time period, gain expertise in the review and analyzing of medical literature?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. When I use the term "medical literature," why don't you tell the jury what that means.
A. Talking about publications that are in typically peer-reviewed journals where scientists, clinicians publish results of

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their research, both pre-clinical research, meaning testing that's not in humans, maybe laboratory research in in vitro, which is test tube, Petri-dish-type testing, benchtop testing, as well as testing in animals and also testing in humans.
For a peer review, a draft publication is submitted to a journal, and a group of peers, if you will, who are experienced in the field that is covered by the specific publication, review the publication, typically will critique it and often will request revisions and decide whether or not that the publication -- that the data in the publication in the paper is worthy of publication.
Q. Okay. Let's shift gears a little bit. I want you to -- I want to talk a little bit about your boards and memberships.
Are there certain boards that you belong to?
A. Yes, either now or in the past.
Q. Right. What are those?
A. I'm currently on the board of the

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Compassion -- of CompassioNow.
Q. What is that?
A. CompassioNow is a nonprofit organization. We have our 10th anniversary this year. It was started with the vision of providing medical care to the world's least served. We've been working in Sub-Saharan Africa, South Africa, Tazania, Zambia, for example, to provide support for nurses and doctors and help to educate local people so that they can help to run community clinics, providing medical supplies, both drugs and various equipment.
There are people in these areas that have -- they don't even have Band-Aids.
Q. I can tell you're proud of that work.
A. I am. It's important. We have served a lot of people, and it's made a difference.
Q. Do you now or have you served on the clinical trials certificate program advisory board?
A. Yes. I did in the past.
Q. What is that?

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A. The intent of that advisory board -- it was run through the California State University system -- was to develop a certification program for people that were both students, usually graduate level students, or people already working in a related field that were interested in furthering their career and getting into clinical development.
And it was intended to be a certification program to train them about how to do clinical trials.
Q. You spoke a little bit about RAPS, which as I understand it, Regulatory Affairs Professional Society.
A. Yes.
Q. And you were a RAPS fellow; is that right?
A. Yes.
Q. What is a RAPS fellow?
A. I'm very honored to be a RAPS fellow. Pardon me. A RAPS fellow is a peer-reviewed credential. RAPS fellows were first designated in 2008. A committee of peers who are senior level professionals who

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have met the highest level of regulatory achievement review one's credentials, and one must have a minimum of 15 years of regulatory experience and then based on one's management and leadership experience and their contributions to the field of regulatory affairs, the committee, which I've actually served on also for several years since becoming a RAPS fellow, makes a determination as to whether or not one qualifies to be a RAPS fellow.

There are, at this point in time as of December 2015, 98.

Q. When did you become a RAPS fellow?

A. 2009.

Q. How many were there in 2009, roughly?

A. 20 to 30 or fewer than 20. I don't recall the specific number.

Q. And that's a Regulatory Affairs Professional Society?

A. A fellow, yes.

Q. And that's for people that have a particular expertise and have been recognized for their abilities in regulatory

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affairs?

MS. SUTHERLAND: Objection. Leading.

THE WITNESS: That's correct. That's correct. One must have achieved the highest level of achievement.

BY MR. GOSS:

Q. Let's talk a little bit about your teaching experience.

First of all, do you have any teaching experience?

A. I do.

Q. And what is your teaching experience?

A. I've taught clinical trials and project management in the clinical trial certificate program that we talked about a short while ago. I've also -- I also was asked to develop and teach. So I'm part-time faculty at the California State University on the Channel Islands campus teaching master's students who are getting their master's degree in biotechnology, a course entitled "Clinical Trials and Quality Assurance."

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Q. What's the regulatory training course faculty?

A. That, if I understand your question, that, through the Drug Information Association, in the past, I have taught in that program.

Q. What is -- I see that you're RAC certified. What is that?

A. That's regulatory affairs certification. That is a certification that is offered through the Regulatory Affairs Professional Society. It is the -- again, is a credential that -- this one in particular is not a peer-reviewed credential.

It's achieved by taking a test that's been designed to test one's level of regulatory expertise, and through the testing, if you pass the test, you can become regulatory affairs certified. And once you become regulatory affairs certified, every three years you're required to submit continuing education and leadership information to show that you're active and still working in the top of your

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field, if you will.

Q. Do you consider yourself a regulatory affairs expert?

A. Yes, I do.

Q. Okay. In addition to all that, you also work on cases like this?

A. Yes.

Q. Okay. Do you accept every case that's presented to you?

A. No, I don't.

Q. Do you charge for your time just like anybody else would?

A. I do.

Q. Charge for your time just like when you consult with a manufacturer?

A. Correct.

Q. Have you testified before in a mesh case?

A. Yes, I have.

Q. Have you been accepted by courts in Texas as an expert in a mesh case?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes, I have.

BY MR. GOSS:

Q. Okay. Let's move on to another

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area. I want to talk with you -- I kind of want to get some definitions down so that the jury kind of understands where we're going with some things.

What is J&J? J&J is a term that the jury is going to hear. What is J&J?

A. Johnson & Johnson.

Q. Okay. What does Johnson & Johnson do?

A. Johnson & Johnson is a company that develops a variety of products. Amongst those products are medical devices as well as pharmaceutical products through various divisions of Johnson & Johnson.

Q. What is Ethicon?

A. Ethicon is a division of Johnson & Johnson. In this case that we're talking about today, it is the division or the part of Johnson & Johnson, if you will, that manufactures and markets the pelvic mesh products.

MS. SUTHERLAND: I'm going to object to foundation just on the response on J&J as to what they do.

BY MR. GOSS:

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Q. What is the FDA?

A. The United States Food and Drug Administration. It is the agency within the federal government that is responsible for oversight of the public health in particular with regard to a number of different products. A large number of products that we all deal with on a daily basis, including not only medical devices and drugs, but certain types of foods, cosmetics, tobacco, veterinary products.

Q. The jury's heard about transvaginal synthetic mesh slings.

A. Yes.

Q. Or mesh slings or slings.

What is that?

A. The transvaginal mesh sling, what we're talking about here today, those slings are made of a plastic, which is polypropylene, for the treatment of stress urinary incontinence.

Q. When we talk about polypropylene, we're talking about plastic.

A. Yes.

MS. SUTHERLAND: Objection.

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BY MR. GOSS:

Q. What's stress urinary incontinence?

A. Stress urinary incontinence, you'll probably hear me refer to it for short as SUI, is involuntary leakage of urine with coughing, for example, jumping, types of exercise that cause intraabdominal pressure.

Q. Is stress urinary incontinence a life-threatening condition?

A. No, it is not.

Q. We're going to talk today about the TVT obturator system. What's the TVT obturator system?

A. It's the tension-free vaginal mesh that is a sling for the treatment of SUI, and it -- tension-free vaginal tape, sometimes the T is -- sometimes is referred to as a tape instead of a sling.

And this particular, the obturator means that it is -- that refers to the insertion technique.

Q. Okay. Let's back up a little bit on that. The jury is going to hear about the TVT retropubic --

A. Yes.

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Q. -- and the TVT obturator.

A. Yes.

Q. Also known as the TVT-O.

A. Yes.

Q. What's the difference?

A. Okay. The tension-free vaginal tape, TVT retropubic, it's the insertion method. And the insertion method is through -- well, it can be inserted two ways.

The insertion begins in the vagina, in the female vagina, and then it exits in the lower abdomen. It can also be inserted suprapubicly so that the insertion begins in the abdomen and then comes through the vagina. So it fits under the urethra, if you will, and the urethra is the tube that leads from the bladder to the exit through which one urinates.

Q. What's the TVT-O obturator or the TVT-O?

A. The insertion route is -- it's an inside-out technique. It starts in the vagina, and instead of going up and the exiting through the abdomen, lower abdomen,

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it exits in the thigh or the groin area going through the obturator -- the obturator membrane and the obturator muscle area.
Q. Which product was developed first by Ethicon?
A. The TVT. The retropubic.
Q. And then did Ethicon develop the TVT-O?
A. Yes.
Q. What's the IFU?
A. The IFU is short for instructions for use. It is what we call professional labeling. It is the cornerstone of risk management because it is the document, the primary communication between the manufacturer of the product, in this case, the TVT-O sling, and the surgeon who's going to be using that product.
And it is intended to provide all of the necessary information to enable the physician to use that product safely and effectively, to consult and advise the patient with regard to the risk, potential risk as well as the potential benefit of the product so that together the patient and

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the -- the physician and the patient can make a determination as to whether or not this is the right product to be used for the patient's treatment of SUI or should an alternative procedure or treatment be used.
Q. What does IFU stand for?
A. Instructions for use.
Q. Okay. And does that come packaged with the product?
A. Yes, it does.
Q. We'll be talking a little about the concept of informed consent.
What is informed consent?
A. Informed consent has -- its -- current day, informed consent really has its origins in the Nuremberg Code following the second world war. The Nuremberg Code was developed as a means of evaluating the scientists and physicians who had participated in experimentation on patients in the -- in Germany during the second world war, and that was the code that was then the beginning of other codes which have been developed.
And the key, the very first point

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of that code, is that human subjects must be -- must be informed about any treatment or any procedure that is going to be done to them and consent. Certainly, that's true in the context of research. It's also true in the context of practice.
In fact, there's a position statement from the American College of Obstetrics and Gynecologists that talks about the concept of respect for persons which is essentially what informed consent does. It's respect for persons in that the individual is informed of all the potential risks and benefits so that they have a right to self-determination for their medical care.
MS. SUTHERLAND: Objection. Nonresponsive.
BY MR. GOSS:
Q. What role does the IFU play in the concept of informed consent?
A. The IFU is the document that provides the information about the product including risks, potential risks, as well as potential benefits, to the surgeon or the --

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in this case, and that information in consenting a patient as to whether or not, in this case the TVT-O, would be used on a particular patient.
That document provides the information for the doctor to share that with the patient, what the risks may be and whether or not the patient makes a decision, self-determination, as to whether or not this is a procedure considering the risks that she wants to undertake.
It also is intended to provide the information that enables the physician, as I mentioned earlier, to make a decision as to whether or not -- because there are alternative treatments available -- whether or not this is the right treatment for a particular patient.
Q. If the IFU is inadequate, what effect does that have on informed consent?
MS. SUTHERLAND: Objection. Speculative.
THE WITNESS: If it is inadequate, then full -- particularly with regard to complications and risks,

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then the patient cannot be truly -- cannot provide true informed consent because information about risks is missing.

BY MR. GOSS:

Q. Does that have an effect on public safety?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes, it does.

///

BY MR. GOSS:

Q. Okay. Let me move on to another topic.

When you were retained in this case, did you conduct an investigation into Ethicon's practices?

A. Yes, I did.

Q. And what did you do to conduct that investigation?

A. I reviewed a large volume of materials, which included deposition testimony of a large number of Ethicon employees. I also evaluated documentation that's been produced in this litigation. I reviewed scientific and medical literature.

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I also evaluated the -- what's called the MAUDE, a manufacturing user facility device experience database, which is a publicly available database of what are called medical device reports, serious adverse events, and malfunctions that could result in serious adverse events that FDA maintained.

I reviewed guidances and regulations that are applicable to the product. That is an overview. Website -- various websites that are relevant.

Q. Were some of the internal documents that you reviewed of Ethicon's, were some of those confidential documents?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes.

BY MR. GOSS:

Q. Were they marked confidential?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes.

BY MR. GOSS:

Q. How many documents do you think you reviewed?

A. Many thousands.

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Q. Okay. In the hundreds of thousands?

MS. SUTHERLAND: Objection. Leading.

THE WITNESS: Very well may be.

BY MR. GOSS:

Q. Okay. Did you review testimony of Ethicon witnesses?

A. Yes.

Q. Did you review trial testimony?

A. Yes, I did.

Q. Did you review deposition testimony?

A. Yes.

Q. Testimony like you're giving today?

A. That's correct.

Q. What areas of Ethicon were -- these employees that were giving their deposition, what areas were they in?

A. A variety of areas. I mentioned earlier that companies like Ethicon have a product project team, and there are different groups that have different expertises that contribute to the development of a project.

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So I have -- the various expertises that would contribute to the development of a project, I've reviewed depositions from people in those different areas which include clinical and medical affairs, pre-clinical, engineers, regulatory as well, senior executives. It would also include quality assurance. Quality.

Q. I'll hand you what's been marked as Exhibit 15.

(Exhibit Number 15 was marked for identification.)

BY MR. GOSS:

Q. This is a slide that I prepared based upon your report and information that you provided to me.

Is this a summary -- first of all, have you seen this slide before?

A. Yes, or one similar, yes.

Q. Okay. And will this assist you in your testimony in explaining to the jury the types of depositions and trial testimony you've reviewed?

A. Yes.

Q. Okay. And is this a list of some

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of the witnesses whose trial testimony and deposition you have reviewed?
A. Yes, it is.
Q. Does that refresh some of your recollection as to what areas some of them are in?
A. Yes. There are people in pre-clinical research, as I mentioned, as well as quality and medical affairs and regulatory affairs and marketing. I think I had not mentioned marketing before. Medical directors. I've also reviewed professional education.
Q. Let me ask you this --
A. Oh. People reporting adverse events and reviewing adverse events.
Q. Did you also review medical literature?
A. Yes.
Q. Okay. What types of medical literature were available to you?
A. The scope of medical literature that's available publicly.
Q. Okay. And did you review peer-reviewed medical literature?

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A. Yes.
Q. And explain to the jury what peer-reviewed medical literature is.
A. Peer-reviewed is the process that means that a publication prior to being accepted for publication is -- someone wishing to publish a paper submits it to an appropriate journal that publishes the type of data that the research that's in that -- that's in a particular paper addresses, and the journal has people who are experienced in that field who review the paper and look at it and critique it and provide feedback to the authors of the publication.
And many times they'll ask questions and have revisions made to the paper prior to its publication, or sometimes if they don't feel that the information in the proposed publication meets the qualifications of the journal or deserves to be published, they'll deny publication.
Q. Did I retain you -- did my firm retain you on behalf of Ms. Ramirez to look at the conduct of Ethicon and determine whether or not that conduct complied with

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industry standards with respect to the development and marketing of the TVT-O?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. And did you endeavor to do that review?
A. Yes, I did.
Q. How many hours do you think that you spent conducting your investigation?
A. Hundreds of hours if you include not just specific for Ms. Ramirez's case but overall for the development of TVT and TVT-O. Hundreds of hours.
Q. In your review of that information and the information that we've talked about so far, did you apply the same methodology in the review of that information that you applied in your everyday work in consulting with other manufacturers and advising them?
A. Yes. In this case, I actually had more information in the context of deposition testimony. When I'm working with companies, I interview the people that I'm working with, but in this context, I had

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enough numerous depositions that I could review that also provided insight to what happened.
Q. You've talked a little bit about some standards in the industry. You spoke this morning about the GHTF principles.
What's GHTF?
A. Global Harmonization Task Force.
Q. We'll talk a little bit about that later.
You spoke about the Blue Book?
A. Yes.
Q. What is that?
A. If I understand your question, the specific Blue Book memorandum that you're talking about is a particular FDA guidance document that -- for medical device labeling that sets the standards for medical device labeling.
Q. In your review and in forming your opinions, did you apply some of those standards to the things that your investigation uncovered?
A. Absolutely.
Q. Okay. Let me shift gears a little

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bit more. I want to talk to you about safety principles. I'm going to hand you some slides. I'm going to hand you what I have marked as Exhibit 16.

(Exhibit Number 16 was marked for identification.)

BY MR. GOSS:

Q. Are these some slides that you assisted me in preparing?

A. Yes.

Q. And do you recognize those slides?

A. Yes, I do.

Q. Okay. Let's talk about the first safety principle. When we say "safety principle," what do we mean?

MS. SUTHERLAND: Objection.

THE WITNESS: That a product is safe for use, that there's a favorable benefit-to-risk ratio.

BY MR. GOSS:

Q. Well, is a safety principle something that a manufacturer should seek to comply with?

MS. SUTHERLAND: Objection.

THE WITNESS: Absolutely.

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BY MR. GOSS:

Q. Let's talk about the first safety principle. "A corporation is required to make sure its products are reasonably safe."

Is that a standard in the industry?

A. Yes, it is.

Q. Okay. And is that a standard in the industry that is set forth in the Global Harmonization Task Force documents?

A. Yes, it is.

Q. Okay. The second safety principle, "A corporation must investigate warning signs that its products may be dangerous and make sure that any problems with the product are fixed in a safe manner."

Is that a safety principle that also has support in the Global Harmonization Task Force documents?

A. Yes, that's correct.

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. Let's talk about the third safety principle. "If a corporation has two products that treat the same condition, and one is safer for patients, the corporation must choose the safest product."

Is that a principle that is supported by the Global Harmonization Task Force standards?

MS. SUTHERLAND: Objection.

THE WITNESS: All other things considered equal, yes.

BY MR. GOSS:

Q. And the fourth safety principle. "Safety of patients has to be the number one priority, not corporate profits."

Is that a safety principle supported by the Global Harmonization Task Force?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes. Patient safety is always number one.

BY MR. GOSS:

Q. Is that a principle that is -- also one that is supported by the credo of J&J and Ethicon?

A. Yes, that is correct.

Q. When you investigated Ethicon -- when you investigated Ethicon, did you find a document that was a Johnson & Johnson credo?

A. Yes, I did.

This was attached to the back of these. Was it intended to be?

Q. I'm handing you what's been marked as Exhibit 17.

(Exhibit Number 17 was marked for identification.)

BY MR. GOSS:

Q. And what is this document?

A. This is the Johnson & Johnson credo.

Q. And are you familiar with this document?

A. Yes, I am.

Q. Let's talk a little bit about it. First of all, do you support this credo?

A. Yes, I do.

Q. Think it's a good idea?

A. It is a good credo.

Q. It says, at the beginning, "We believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers and all others who use our products and services."

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Is that consistent with the safety principles we just discussed?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
BY MR. GOSS:
Q. In your investigation, did you find that Johnson & Johnson lived up or Ethicon lived up to this credo?
MS. SUTHERLAND: Objection.
THE WITNESS: I found that they did not live up to this credo.
BY MR. GOSS:
Q. With respect to their development in marketing of the TVT-O?
MS. SUTHERLAND: Objection.
THE WITNESS: That is correct.
BY MR. GOSS:
Q. Okay. You've talked a little bit about the label. Who is responsible for making sure that the label is accurate?
A. The primary responsibility is that of the manufacturer.
Q. And I've heard the concept called "owning the label." What's that mean?
A. That the manufacturer -- it is

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their product. The manufacturer owns the label. It is a component of the product, in this case, the TVT-O. And owning the TVT-O, the company, Ethicon, also owns the label, meaning that it is responsible for making sure that that professional labeling is -- any type of labeling that is associated with its product is truthful and accurate and complete and not misleading.
Q. The buck stops with the manufacturer?
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. The safety principles that we've talked about, are those safety principles part of the standard of care for a manufacturer?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, they are.
BY MR. GOSS:
Q. Would you consider the credo that putting patients first, first responsibility to patients, the credo adopted by this company, would you consider that the

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standard of care?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. In your investigation of Ethicon's files in review of discovery in this case and all the things that we've just discussed that you reviewed in applying the standard of care and the documents reflecting the standard of care, did you reach an opinion regarding whether Ethicon violated the standard of care in its marketing of the MCM, TVT obturator system?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, I did.
BY MR. GOSS:
Q. And what is that opinion?
A. They violated the standard of care in several ways.
Q. Did you reach an opinion whether Ethicon violated the standard of care by failing to conduct appropriate testing to support the safe and effective use of the TVT obturator system?
MS. SUTHERLAND: Objection.

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THE WITNESS: Yes.
BY MR. GOSS:
Q. What is that opinion?
MS. SUTHERLAND: Same objection.
THE WITNESS: They failed to act according to the standard of care.
BY MR. GOSS:
Q. Did you reach an opinion whether the labeling for the TVT obturator system was inadequate?
A. Yes, I did.
Q. Due to failure to warn?
A. Yes.
Q. What's that opinion?
MS. SUTHERLAND: Objection.
THE WITNESS: The labeling was inadequate.
BY MR. GOSS:
Q. Did you reach an opinion as to whether the label was false or misleading?
A. Yes, I did.
Q. What is that opinion?
MS. SUTHERLAND: Objection.
THE WITNESS: The labeling was

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false and misleading.
BY MR. GOSS:
Q. Did you reach an opinion as to whether Ethicon failed to meet the post-market vigilant standard of care in management of risk?
A. Yes, I did.
Q. What is that opinion?
MS. SUTHERLAND: Objection.
THE WITNESS: They failed to meet the post-market vigilant standard of care and manage risk appropriately.
BY MR. GOSS:
Q. You have prepared a report in this case?
A. Yes.
Q. Did you prepare a supplemental report as well?
A. Yes, I did.
MR. GOSS: Did we mark those already?
MS. SUTHERLAND: Yeah.
THE WITNESS: I'm not sure Exhibit 2 to the March supplemental report was marked.

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BY MR. GOSS:
Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4.
A. Yes.
Q. And did that Pence Exhibit 4 supplement Pence Exhibit 3?
A. Yes.
Q. And is Exhibit 6 also a part of your report, a supplemental report?
A. Yes. It's March of this year. A supplemental report. And Exhibit 6 is just the body of the report without the exhibits.
Q. And what is Exhibit 7?
A. Exhibit 7 is Exhibit 1, applicable industry standards, to the March, 2016, supplemental report which was Exhibit 6. There is an Exhibit 2, which we have not marked.
Q. Okay. I'm going to hand you what's been marked as Exhibit 21.
Is this the Exhibit 2 that you just referenced?
A. Yes.
Q. Okay.

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THE REPORTER: Excuse me. Did you say Exhibit 21?
MR. GOSS: You know what? I'm sorry. I grabbed the wrong one. I'm going to re-mark Exhibit 21 as Exhibit 18.
(Exhibit Number 18 was marked for identification.)
BY MR. GOSS:
Q. Again, is Exhibit 18 the Exhibit 2 you just referenced?
A. Yes, it is.
Q. Okay. All the opinions that you've given today and that you are going to give today, have they all been held to a reasonable degree of scientific or professional certainty?
A. Yes, they have.
Q. We've talked a little bit about the TVT-O. What was it designed to treat?
A. Stress urinary incontinence.
Q. When did it come on the market?
A. The very end of 2003, early 2004.
Q. And was the TVT retropubic already on the market?

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A. Yes.
Q. Do you recall how long it had been on the market?
A. Since 1998.
Q. What type of mesh is used in the TVT-O?
A. Polypropylene mesh.
Q. There's going to be some discussion today about MCM-cut mesh.
By the way, is Prolene mesh in the TVT-O?
A. Yes. It's Prolene polypropylene mesh.
Q. Okay. And there's going to be -- there's been some discussion, and we're going to have some more discussion about the manner in which the Prolene mesh was cut by Ethicon, and we'll discuss what's called MCM.
Do you know what that is?
A. Yes, I do.
Q. What is that?
A. Mechanically cut mesh.
Q. Okay. And then there's going to be a discussion of LCM.

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Do you know what that is?
A. Yes.
Q. What is that?
A. Laser-cut mesh.
Q. Are they two different methods of cutting?
A. Yes.
Q. Okay. Do you know what type of TVT-O mesh was implanted in Jennifer Ramirez on September 17, 2010?
A. Yes, I do.
Q. What was it?
A. A mechanically cut mesh.
Q. And it was a TVT-O?
A. That's correct.
Q. Okay. I'm going to hand you what's been marked as Exhibit 19.
(Exhibit Number 19 was marked for identification.)
BY MR. GOSS:
Q. What is that document?
A. This is a document that has a sticker from the TVT-O device that was implanted in Ms. Ramirez. The document is a Baptist Health System document dated 9/17/10

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showing the surgeon's name, Dr. C. Reyes -- or C. Reyes, implant location, vagina.
Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh?
A. Yes.
Q. And how can you tell by looking at this document that it was mechanically cut?
A. The number that's on the sticker from the mesh that was implanted, 810081, does not have an L at the end, and when it's laser-cut mesh, an L is included at the end of that series of numbers.
Q. How did you learn that?
A. Through review of the Ethicon documentation.
Q. In conducting your investigation into Ethicon's internal documents, were you able to determine the reason Ethicon developed the TVT-O?
MS. SUTHERLAND: Objection.
THE WITNESS: The TVT-O?
BY MR. GOSS:
Q. Yes.

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A. Yes.
Q. And what was that reason?
MS. SUTHERLAND: Objection.
THE WITNESS: The idea was to reduce the numbers of bladder perforations that were occurring.
BY MR. GOSS:
Q. What was happening in the market?
MS. SUTHERLAND: Objection.
THE WITNESS: What was happening in the market with the TVT-O was Ethicon had enjoyed about five years of the market for stress urinary incontinence slings, and competitors were coming on the market, and in particular, a couple of other companies had marketed devices with an obturator approach, and that was hoped that it would be safer than the retropubic approach because of the numbers of bladder perforations in particular that can occur and have occurred with the retropubic approach.
And so in order to retain and not lose market share, the company

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decided that they needed to enter the competitive market space with an obturator approach.
BY MR. GOSS:
Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years.
With respect to what product?
A. The TVT retropubic.
Q. Not the O?
A. That's correct.
Q. Okay. And were competitors entering the market?
A. Yes.
Q. Did you see any documents that reflected that Ethicon was concerned about the competitors entering the market?
A. Yes, I did.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. I'm handing you what's been marked as Exhibit 20.
(Exhibit Number 20 was marked for identification.)

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BY MR. GOSS:
Q. Is that a document that you discovered in Ethicon's files?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. And is this a document that you relied upon in forming your opinions in this case?
A. Yes.
Q. And what's the date of this document?
A. 14 February, 2003.
Q. And the document's regarding Project Mulberry.
What is that?
A. Project Mulberry was the project name given to the development of TVT-O.
Q. And let's just start with the executive summary and the strategic rationale. Is there anything under strategic rationale with respect to this document that you found important in your opinions today?
A. Yes.

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Q. What's that?
A. The rationale that we were just discussing for development of the TVT-O being competitive pressure.
Q. It says, "The rationale for Project Mulberry is to drive and defend Gynecare sales of TVT, hereafter referred to as TVT."
And, again, Project Mulberry is the TVT-O?
A. That's correct.
Q. And it goes on to say, "TVT is under competitive pressure, as evidenced by a decline in category share of revenue of 15 percent in Europe and the U.S., over the last two years. The competition comes from "me-too" versions of TVT."
Did you find that important?
A. Yes.
Q. Why?
MS. SUTHERLAND: Objection.
THE WITNESS: That was a key rationale to the development of the TVT-O. It was to preserve market share.
BY MR. GOSS:
Q. Okay. Is there anything that

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you've seen in this document where it reflects that their concern was trying to develop a better product for their patients?
MS. SUTHERLAND: Objection.
MR. GOSS: Let me re-ask that.
BY MR. GOSS:
Q. Under this strategic rationale, does it discuss how much they thought they would lose if they -- if things continued as they were with the TVT franchise?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it does.
BY MR. GOSS:
Q. What was that?
A. It was $8 million, if I recall correctly, yes.
Q. Under the financial summary, does it reflect how much they thought they could profit if they launched a product like the TVT-O?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it does.
BY MR. GOSS:
Q. What did they project as year of sales of TVT-O?

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MS. SUTHERLAND: Objection.
THE WITNESS: I'm sorry?
BY MR. GOSS:
Q. By 2010, were they projecting sales?
A. Yes.
Q. Of how much?
A. Peak year sales of the transobturator products exceeding $34 million, of which 60 percent would be incremental over the current TVT sales projections.
Q. Okay. So to summarize this, is it fair to summarize this first page of this document to be that Ethicon reflects it was concerned about losing market share?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. It was concerned that it was going to have lost profit of $8 million?
MS. SUTHERLAND: Objection.
THE WITNESS: Correct.
BY MR. GOSS:
Q. But if they could develop a TVT-O,

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they could have products sales exceeding 34 million by 2010?
MS. SUTHERLAND: Objection.
THE WITNESS: Correct.
BY MR. GOSS:
Q. Okay. Let's go to the second page. I'm going to ask you about the first line of that second page. It says, "The assumptions used to make product sales forecasts are as follows: U.S. assumes introduction of Mulberry in quarter 1 2005 after six months of clinical data is available."
What does that mean?
MS. SUTHERLAND: Objection.
THE WITNESS: That means at the time this document was prepared in February of 2003, that the company intended to introduce TVT-O once they had six months of clinical testing data available.
BY MR. GOSS:
Q. Is that a good thing?
MS. SUTHERLAND: Objection.
THE WITNESS: That's a good thing, yes.

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BY MR. GOSS:
Q. Is that what you would expect a company -- I'm sorry.
Is that what you would expect a design -- a device company -- let me start over.
Is that what you would expect a device manufacturer to do?
A. Absolutely.
Q. To conduct six months clinical data?
A. Minimally six months.
Q. Okay. We'll get to this a little bit later. Did they do that?
A. No, they did not. Not beyond what the inventor of the product had already done with the prototype.
Q. Let's go to the Bates number on that exhibit that is -- it's page 7. Bates number ends at 53.
Do you see "Risk Assessment"?
A. Yes.
Q. Under "Clinical," what does it have as risk assessments?
MS. SUTHERLAND: Objection.

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The document speaks for itself.
THE WITNESS: Three things. That it's a new procedure. Secondly, the obturator bundle because, again, if I might explain that, the insertion route is a different route, and in the obturator bundle, they're the obturator nerve and obturator vessels which, if those are perforated, could cause issues, safety issues, for the patient, present potential risks.
And the third is future, as they term it, radical developments, for example, needle-less TVT and growth factors.
BY MR. GOSS:
Q. So in 2003, just so I'm clear, is Ethicon evaluating already under risk assessment, clinical issues and risks with the obturator bundle?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Do you find that important?
A. Yes.

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Q. Why?
A. Because those risks in order -- it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk assessment to assure that there's a favorable benefit/risk ratio, and that includes an assessment of potential risks, and the way you assess that risk is through clinical testing.
Q. Did -- in your investigation of the files of Ethicon, did you see anywhere where they -- where it upset -- where it assessed the risk of obturator bundle injury prior to launching this product?
A. No. Certainly not in clinical testing.
Q. Would a reasonable and prudent manufacturer have done that assessment?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
(Exhibit Number 21 was marked for identification.)
BY MR. GOSS:
Q. I'm going to hand you what's been

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marked as Pence Exhibit 21. And is this a document that you reviewed -- first of all, did you find this in Ethicon's files?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Is this a document that you reviewed and relied upon in coming up with your opinions in this case?
A. Yes, it is.
Q. Is this document dated April 14, 2003?
A. Yes, it is.
Q. Is this an Ethicon document?
A. Yes.
Q. Came out of their files?
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. Is Brian -- I believe Brian Luscombe, is he the U.S. products director?
A. Yes. To the best of my recollection, that is correct.
Q. And he's on this email string. This is a long email string; right?

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A. Yes, it is.
Q. As I understand, the way that you read these documents out of their files that are email strings is you start from the back and work your way forward; is that correct?
A. Correct.
Q. So let's do that. So start at the bottom of the second page that has Bates number 94 at the end.
Do you know where I am?
A. I am there too.
Q. Okay. And this is an email from Brian Luscombe to Cheryl Bogardus. I believe -- do you recognize she is worldwide marketing director?
A. Yes. That's my recollection as well.
Q. And Brian Luscombe, I believe, he was U.S. product director; is that right?
A. Yes. To the best of my recollection, that's correct.
Q. It says, "Cheryl, I understand that the Gynecare board made the decision that clinicals will not be required for Mulberry."

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Again, what's Mulberry?
A. That's the project name for the TVT-O.
Q. "Can you please clarify whether or not post-market introduction studies are acceptable or not? If we only have ex-U.S. data, won't this limit us? Brian."
Was this document -- was that email important for your opinions?
MS. SUTHERLAND: Objection. The document speaks for itself.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Why?
A. Because as the risk assessment noted in the document we just reviewed, Exhibit 20, the -- there are risks with a new procedure, risks with the obturator approach, particularly with regard to the obturator bundle, and clinical testing in February of 2003 was intended to be done.
And in this document, we learn two months later, almost two months later to the date, that the Gynecare board had made the decisions -- the decision that clinicals

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would not be done, which means that these risks would not be assessed in human testing prior to marketing.
Q. Is that decision by the Gynecare board in violation of standards in the industry?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Why is that?
A. Once again, one has to ensure the safety and effectiveness of one's product, and in order to do that, one has to do a clinical evaluation of data that's available and based on the data that's available, make a determination as to whether or not there's a favorable benefit to risk for use of this device.
And if one does not have that data, then that's a violation of we refer to as the essential principles of safety as well as performance, and in order to get the type of information necessary, they needed to do clinical testing.
Q. Okay. Let's talk about the email

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right following this one.
A. Okay.
Q. Okay. So to set the stage -- to set the stage, we know two months ago there was a projection that there would be a six months of clinicals done before launch.
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. And then we have an email here where we learn and you learn in your investigation that the Gynecare board made the decision that they weren't going to do the clinical testing.
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. Okay. So let's get to the next email. Cheryl Bogardus, I assume she was the same Cheryl from below; right?
A. Yes.
Q. Writing back to Brian Luscombe, responding to the previous email, she says -- let's get to the second sentence in the second paragraph. "To protect our

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market share, we need to be ready to launch. So the development process should not require clinicals."
Do you find that sentence important?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, I do.
BY MR. GOSS:
Q. Why is that important?
A. Because the key factors we discussed earlier with regard to safety principles is patient safety and ensuring that the product is safe. The first point of care of a company is not protecting market share. While that's important, the first point is to make sure that the product is safe. You don't market a product without knowing and justifying that it's safe and effective.
Q. Should a company ever forego recommended clinical testing so that it could protect its market share?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:

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Q. Should a company ever put market share and profits over safety?
MS. SUTHERLAND: Objection.
THE WITNESS: Never.
BY MR. GOSS:
Q. Is that a violation of the industry standards?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
///
BY MR. GOSS:
Q. Would that be a violation of Ethicon's own credo?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
BY MR. GOSS:
Q. Would that be a violation of the Global Harmonization Task Force?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it would.
(Exhibit Number 22 was marked for identification.)
BY MR. GOSS:
Q. I'll hand you what's been marked as Pence Exhibit 22.

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Is that a document that you found in Ethicon's files?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
BY MR. GOSS:
Q. Is this an Ethicon document?
A. Yes, it is.
Q. Is this a document that you reviewed in connection with forming your opinions?
A. Yes, it is.
Q. Is it a document you relied upon in forming your opinions?
A. Yes, it is.
Q. This document is dated June 24, 2003, from a Ronnie Toddywala. I believe he's vice president of Gynecare.
Is that what you understand?
A. Yes. Gynecare research and development.
Q. It says so on the bottom of the document.
A. Yes.
Q. I'm trying to figure out who some of these other people are. Is Cheryl

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Bogardus, we just spoke about her. Is she the worldwide marketing director?
A. Yes. That's my understanding, yes.
Q. What about Axel Arnaud? I see he is cc'd. Who's that?
A. He was actually -- for the TVT-O, he was actually the person who identified the -- Dr. De Leval who is the inventor of the in-out procedure that is the TVT-O procedure.
Q. Was he the head of medical affairs?
A. In Europe, yes.
Q. Okay. This document says, "Dear All, as you know, Project Mulberry" -- again, is that the TVT-O?
A. Yes.
Q. -- "is critical to Gynecare's success in the incontinence marketplace. This team has been charged with the breakthrough goal of completing this project within nine months. We must make this project happen in a short period of time. You play a critical role in bringing this endeavor."
First of all, do you find that

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important --
MS. SUTHERLAND: Objection. The document speaks for itself.
BY MR. GOSS:
Q. -- in forming your opinion?
MS. SUTHERLAND: Speaks for itself.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Why are those statements important to you in forming your opinions?
A. Notably, the breakthrough goal is to complete the project within nine months, and this project was initially, if I recall correctly, this project was intended to have 24 months.
And part of that time, of course, would have been doing the clinical testing that we've talked about. So now for competitive reasons, the decision has been made that they must launch the product within nine months.
Q. Again, would a reasonable and prudent manufacturer decrease its launch time by cutting clinical studies that relate

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to safety?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. Did you ever see any documents that reflected how much the French market was estimated to lose as a result of the competitors entering the market in the TVT?
A. Yes.
Q. What percentage of the market were they anticipating losing?
A. If I recall correctly, it was 30 percent.
Q. Is that substantial for a manufacturer?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
MR. GOSS: I'm sorry. I only have one copy, but I think you've seen it.
MS. SUTHERLAND: It's not like I have a whole lot of time when you get done to ask questions about it.
MR. GOSS: Yeah.
BY MR. GOSS:

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Q. I'm going to hand you what's been marked as Exhibit 23.
(Exhibit Number 23 was marked for identification.)
MR. GOSS: Do you want to look at it first.
MS. SUTHERLAND: Just to see.
MR. GOSS: I'm only using this one to liven you up a little bit.
MS. SUTHERLAND: I'm engrossed. Can you not tell? Am I not objecting enough?
BY MR. GOSS:
Q. Okay. Is this a document that you reviewed that came from Ethicon's files?
A. Yes.
Q. And it says it's a sales training launch meeting, January 22 through 23, 2004, Bridgewater, New Jersey.
What's a sales training launch meeting? What is that?
A. This is a presentation to the sales representatives that will be detailing physicians, telling them about this product with the intent of the physicians buying

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this product.
Q. Okay. And is the product on the market yet?
A. It was launched in this period of time. It was cleared to go to the market in December of 2003. So this is -- this is the --
Q. The TVT-O?
A. The TVT-O. This is the sales training right after the product was cleared so that it could be sold in the U.S.
Q. Okay. And is this a PowerPoint?
A. Yes.
Q. Okay. And, again, they're using this to train their sales team?
A. Yes.
Q. Okay. Let's turn to -- the pages aren't numbered, but can you find the top ten reasons to pursue the TVT obturator approach.
A. Sorry. Some of them are upside down. I'm trying to find them.
Q. Let me find it for you.
By the way, did you review this document in preparation for your opinions?

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A. I did.
MS. SUTHERLAND: I'll object that the document speaks for itself.
MR. GOSS: I'll let you have that objection for every document.
MS. SUTHERLAND: May I have a continuing objection for every Ethicon document that you use?
MR. GOSS: Sure.
I do agree with your statement about the document earlier.
MS. SUTHERLAND: What did I say?
MR. GOSS: That it's gross.
Strike that conversation.
BY MR. GOSS:
Q. Okay. Here you go.
All right. Now, this sales document where they're teaching -- where Ethicon is teaching its salespeople about the TVT obturator and that approach in anticipation of going out and selling the product, they have a top ten reasons to pursue Gynecare TVT obturator approach. And we'll go through a few of these.

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Number 9, for example, says, "Since the needles don't enter the retropubic space, bladder perforation should be reduced."
That's what you said earlier?
A. That's correct.
Q. It's a good scientific reason?
A. Yes, it is.
Q. Says one of the inventors, number 4, "Doesn't like the obturator approach."
That's a competitor doesn't like it; right?
A. Yes.
Q. Number 5, it says, "The hammock shape of the sling may result in less obstructive symptoms since it's hard to over-compress the urethra with the obturator sling."
Scientific reason?
A. Yes. Medical reason, yes.
Q. And what did they give as the number one reason as to why they should pursue the TVT obturator approach?
MS. SUTHERLAND: Objection.
THE WITNESS: "Mama needs a new

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pair of shoes."
BY MR. GOSS:
Q. In other words, for profit?
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. Should a company ever encourage -- strike that.
Would a reasonable and prudent manufacturer ever encourage its employees to sell its product solely for profit over safety?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
MS. SUTHERLAND: If you're switching, can I run down the hall real quick?
MR. GOSS: Sure. Let's take a five-minute break.
MS. SUTHERLAND: Yeah.
THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately 6:29 p.m.
(Recess taken from

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6:29 p.m. to 6:36 p.m.)
THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 6:36 p.m.
BY MR. GOSS:
Q. Dr. Pence, I should have done this early on. I'll go ahead and do it now. We keep talking about the Global Harmonization Task Force, and we spent a lot of time on that this morning, and I'm not sure if this has been marked, but I'm going to mark another one just in case.
I've marked Pence Exhibit 24.
(Exhibit Number 24 was marked for identification.)
BY MR. GOSS:
Q. So I've handed you what has been marked as Pence Exhibit 24. And when we've talked about the Global Harmonization Task Force, is this one of the documents we talked about?
A. Yes, it is.
Q. Its title is "Essential Principles of Safety and Performance of Medical Devices," endorsed by the Global

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Harmonization Task Force dated May 20, 2005.
A. That's correct.
Q. And this is one of the documents that you discussed previously that provides the standard of care with respect to device manufacturers?
A. Yes. It is an international standard of care.
Q. Okay. And this is something that you applied in giving your opinions?
A. Yes.
Q. Okay. Let's go to page 8 of that document. Go to page 8 of that document and talking about under a section called "Essential Principles of Safety and Performance of Medical Devices." It says, "General Requirements. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, and where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients or the safety and health of users

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or, where applicable, other persons provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits of the patient and are compatible with a high level of protection of health and safety."
That's a long way of saying -- isn't it? -- that manufacturers should market safe products?
MS. SUTHERLAND: Objection.
THE WITNESS: Safe, and as I mentioned before, that have a favorable benefit-to-risk ratio.
BY MR. GOSS:
Q. Okay. I got on objection. Let me try to fix this.
What are they saying there in Section 5.1?
A. They're saying that for the intended use of a medical device, that they should be designed and produced in such a way that for their intended use, they don't compromise -- they don't cause undue risk to the patient or users of the device either and that, again, as I've specified before,

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that one has to always look at the potential risks versus the potential benefits and assure that there's a favorable benefit-to-risk ratio.
In other words, that the benefits exceed the potential risks and any risks are acceptable.
Q. We talked about safety principles earlier in Exhibit 16.
A. Yes.
Q. Does that support your safety principle number 1?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Like the first line, "A corporation is required to make sure its products are reasonably safe"?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Does it also support "Safety of patients has to be the number one priority, not corporate profits"?
A. Yes, it does.

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MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Let me ask you -- let's go down that document some more.
MS. SUTHERLAND: Can I have a continuing objection, again, to just reading the GHTF documents as well as you already gave me the one on the Ethicon documents.
MR. GOSS: Sure.
How am I supposed to use it if I can't read it? Am I supposed to -- mental telepathy to the --
MS. SUTHERLAND: You're supposed to ask her what it means if it needs explanation by an expert.
BY MR. GOSS:
Q. Let talk about Section 5.2 of the general requirements, and I'll ask the court to let us publish 5.2 to the jury.
Tell me what 5.2 means.
A. The essence of this is that a medical device manufacturer must do a risk assessment of its product to, again, make sure that the risks are acceptable for

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the -- how the product is designed and how it's manufactured, and to do that, they have to identify known or foreseeable potential risks, estimate those risks, eliminate them as far as they can, reduce any remaining risks by taking adequate protection measures and very importantly, according to what we've been discussing with regard to labeling, the key there is inform users of any residual risks.
Q. Does that support the second page of your safety principles in Exhibit 16 that a corporation must investigate warning signs that its products may be dangerous and make sure that any problems with the product are fixed in a safe manner?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it does.
BY MR. GOSS:
Q. Okay. Now I'd like for you to look at page 9 of 15 on that exhibit, which is Exhibit 24. In particular, where it says that "They should eliminate risks as far as reasonably practicable through inherently safe design and manufacture."

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A. Yes.
Q. What does that mean?
A. That means in the design of the device and how it's actually produced, that they do a risk assessment and anything that they can do to control risks in how the device is designed and manufactured, they are supposed to do.
Q. Does that support, back to Exhibit 16, safety principles, the safety principle on page 3 of Exhibit 16, "If a corporation has two products that treat the same condition, and one is safer for the patients, the corporation must choose the safest product"?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes. That would be consistent with what we just read.
BY MR. GOSS:
Q. Okay. I'm going to hand you what's been marked as Exhibit 25.
(Exhibit Number 25 was marked for identification.)
MS. SUTHERLAND: I've seen it.
BY MR. GOSS:

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Q. Is this, again, another Global Harmonization Task Force document?
A. Yes.
Q. Titled "Clinical Evaluation"?
A. That's correct.
Q. Dated May, 2007?
A. That's correct.
Q. Is this one of the documents that you relied upon for the standard of care?
A. Yes.
Q. Let me turn you to -- direct you to page 4 of 28. And you talked a little bit earlier about clinical evaluation.
A. Yes.
Q. And what does this tell us in that third section, third paragraph there about clinical evaluation as far as the standard of care is described in this document?
MS. SUTHERLAND: Objection.
THE WITNESS: Are you talking about the first paragraph after "Why is clinical evaluation important?"
BY MR. GOSS:
Q. Right.
A. Clinical evaluation is one of the

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methods by which one assures that a device satisfies the essential principles of safety and performance. Basically, it's through clinical testing that you determine whether the product is safe and whether it's effective in humans.
Q. Okay. And does it talk about minimizing adverse events?
A. Yes, it does. And clinical evaluation, in this context, includes clinical data from different sources. Clinical testing as well as commercial experience and also the scientific and medical literature, the peer-reviewed publications that we talked about.
Q. Okay. Let's shift gears. Let's go to -- I want to talk with you briefly about the 510(k) process.
What are the two processes by which a medical device can come to market?
A. The 510(k) process, if an application is required to be submitted to the FDA, either a -- what's called a 510(k), a pre-market notification, or a pre-market approval application, which is referred to

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as a PMA.
Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?
A. There are a number of differences between the two. Probably the key one is that a 510(k) pre-market notification is submitted to FDA to get a clearance of the product to market based on substantial equivalence to what is termed a predicate product, a product that's already legally on the market that is similar to the device that is the subject device that the company intends to market.
Where the pre-market approval application is submitted to the FDA and includes a much larger volume of data, and the data submitted is reviewed by FDA in such a way that it is an independent demonstration -- there must be an independent demonstration of safety and effectiveness, and a PMA product, if FDA accepts it for -- authorizes it to be marketed is approved versus cleared.
Q. Can a manufacturer that has

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received 510(k) clearance represent that its product has received approval?
A. No.
Q. Why is that?
A. There's a specific regulation that specifies that one cannot give -- infer that a 510(k) clearance constitutes an approval by FDA.
Q. What type of studies are typically done with PMA approval?
A. Almost all PMAs require clinical human testing.
Q. Okay. But a product -- a device that's gone through 510(k) clearance have done any clinical testing?
MS. SUTHERLAND: Objection.
THE WITNESS: Only about 10 to 15 percent require clinical testing.
BY MR. GOSS:
Q. If a manufacturer wanted to do clinical testing before seeking 510(k) clearance, could it?
A. Absolutely.
Q. Okay. How long does it take to get pre-market approval versus clearance?

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MS. SUTHERLAND: Objection.
THE WITNESS: The average -- the -- typically -- well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in approximately a month, just under a month. The overall average, depending on which year you look at, is around 90 to 140 days.
The pre-market approval review at FDA can require upwards of 300, 350 days, and generally speaking, it's anywhere from two-and-a-half to three-and-a-half or four times the amount of time that FDA spends reviewing a PMA by contrast to a traditional 510(k), and the TVT-O was not a traditional. It was a special which means less information, less time.
BY MR. GOSS:
Q. Just so it's clear for the jury, was there ever an independent determination by the FDA that the TVT-O was safe or it was efficacious?

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MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. Is there any room for debate about that?
A. No.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Let's talk a little bit about the TVT-O. And you talked a little bit this morning with defense counsel about Prolene mesh, and there was some discussion about fraying.
Do you recall that?
A. Yes, I do.
Q. In your investigations of -- in your investigation of Ethicon's files, did you uncover any documents that discussed any complaints about the Prolene mesh product fraying?
A. Yes, I did.
Q. Did you uncover any documents that discussed particle loss with respect to Prolene mesh?
A. Yes.

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Q. Did you review any documents that discussed the difference between MCM and LCM with respect to fraying and particle loss?
A. Yes, I did.
Q. Did those documents form a basis of your opinions that you're giving today?
A. Yes, they did.
Q. I'm going to hand you what's been marked as Pence Exhibit 26.
///
(Exhibit Number 26 was marked for identification.)
BY MR. GOSS:
Q. Is that a document that you reviewed from Ethicon's files?
A. Yes, it is.
Q. And is this a document relating to a TVT device?
A. Yes, it is.
Q. What's the date of this document?
A. October 12, 2005.
Q. And who is Carol Holloway?
A. She's a product complaint analyst in worldwide customer quality.
Q. By the way, when we talk about TVT

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and TVT-O, do they use the same mesh?
A. Yes, they do.
Q. Okay. So what is this document, and why was it important to you?
MS. SUTHERLAND: Objection.
THE WITNESS: This is a document about a customer's experience with a TVT device where there was unravelling. It's a complaint where unravelling of the tape occurred, and the tape became particles, and after implantation of the TVT device, the staff found remaining particles that had been lost from the mesh in the box.
BY MR. GOSS:
Q. And Carol -- this is a letter from Carol Holloway. She is a product complaint analyst worldwide customer quality for Gynecare.
Is Gynecare a part of J&J and Ethicon?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. I believe it's a women's division

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or something?
A. That's correct.
Q. And one of the sentences -- explain to the jury this sentence: "Fraying is inherent in the product" -- this is Ms. Holloway for the Gynecare talking. "Fraying is inherent in the product based upon the mesh construction."
What does that mean, "Fraying is inherent in the product"?
MS. SUTHERLAND: Objection.
THE WITNESS: The way the product is designed and with the mechanical cutting, what occurs is that there is -- the term that has been used by Ethicon is a degradation of the mesh structure so that the structure particularly when they -- there's particle loss even without stretching but when -- particularly when the product is stretched, that the structure along the edges of the mesh is lost, and the product can rope and curl and particles fall off.
BY MR. GOSS:

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Q. Under the re line there, it has a lot number. Can you tell from that lot number whether this lot -- whether this product that's being discussed in this exhibit is mechanical cut?
A. Yes.
Q. And what is it?
A. It's mechanically cut.
Q. And how do you know that?
A. There's no L for laser cut as well as in October, 2005, the laser cut was not yet available.
Q. So what should a reasonable, prudent manufacturer do when it receives a letter like this?
MS. SUTHERLAND: Objection.
THE WITNESS: There's a number of different things it should do. It should do further investigation. It should open up corrective and preventive action, determine what the cause of this is, and then look at what it can do to mitigate risks.
And it should investigate, like this loss of particles and the

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stretching that occurs, whether or not -- how that -- I should say how that impacts the safety and effectiveness of the tape when implanted.
BY MR. GOSS:
Q. Let me hand you what's been marked as Exhibit 27 to your deposition.
(Exhibit Number 27 was marked for identification.)
///
BY MR. GOSS:
Q. Is that a document that you reviewed from Ethicon's files?
A. Yes, it is.
Q. And is this a document that you relied upon in forming your opinions today?
A. Yes, it is.
Q. And this document is from Dan Smith.
Do you know who Dan Smith is?
A. Yes, I do.
Q. Who is he?
A. He is a lead engineer. If I recall correctly, he was a project lead on the TVT-O and been with the company

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approximately 36 years. Engineering fellow at this point, I believe.
Q. So, and he's writing to Janice Burns. I believe she's with -- @ethgb means Ethicon Great Britain; is that right?
A. Yes, that's my understanding.
Q. And, again, with these emails, we start from the back, which should be the second page; right?
A. Yes.
Q. And that appears to be, on the second page, an email from Bernhard Fischer, who appears to be from marketing Gynecare and Breast Care in Vienna.
A. Correct.
Q. And he is writing Janice Burns in Great Britain regarding TVT complaints; is that right?
A. Yes.
Q. And is this email something that you relied upon in forming your opinions?
A. Yes, it is.
Q. And is this time period a time period before there was laser-cut mesh?
A. Yes, it is.

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Q. So the mesh we're talking about here would be mechanically cut mesh?
A. Yes.
Q. Okay. And what's Janice Burns -- what is Bernhard Fischer explaining to Janice Burns in this email?
MS. SUTHERLAND: Objection.
THE WITNESS: It's about two TVT complaints, both dealing with the same issue. One with the retropubic -- the TVT retropubic, and one with the TVT obturator, the TVT-O, and it has to do with a small blue particles. The mesh was blue, falling off the mesh, and they term it as if the mesh was brittle. It has to do with the particle loss and fraying that we were just discussing.
BY MR. GOSS:
Q. Okay. Let's go back to the front page now and look at the end of the email where Dan Smith is writing to Janice Burns. He's responding to this situation; is that right?
A. Yes.
Q. And he writes, "This is not new,

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and was exactly the original issue that stopped TVT blue for months. The fix, I'm not sure how complete, is to cut the mesh using ultrasonics, but it has not been validated. I'm not sure where it sits on the operations priority list."

What does that mean?

MS. SUTHERLAND: Objection.

THE WITNESS: It means that the company has identified a way to fix the fraying, but they've not implemented it.

BY MR. GOSS:

Q. Okay. In the company documents, do they sometimes use ultrasonic and LCM interchangeably?

A. They're different, but they've used ultrasonic cutting to test material that they -- that they've -- where they've later marketed laser-cut mesh. They've done the testing with ultrasonically cut mesh.

Q. Okay. So go down to the third -- I guess the fourth paragraph there. "This is not going away any time soon, and competition will have a field day. Major damage control offensive needs to start to

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educate the reps and the surgeons upfront that they will see blue shit, and it is okay. This is why I wanted to launch TVT-O in clear."

Is there anything in that sentence that's important to your opinions?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes.

BY MR. GOSS:

Q. What's that?

A. They've identified this shedding of particles as an issue, and yet their concern is more about it not being noticeable to surgeons than actually doing an evaluation and the appropriate testing to determine whether or not this is a safety risk or an effectiveness risk as well for the patients in whom this faulty product is implanted.

Q. Is that a violation of the safety principles we've discussed today?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes, it is.

BY MR. GOSS:

Q. Should a -- Dan Smith is saying here that he wanted the TVT-O to be clear.

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Should a manufacturer ever manufacture a product so that a defect could not be apparent to the user?

MS. SUTHERLAND: Objection.

THE WITNESS: No.

BY MR. GOSS:

Q. Would that be a violation of standards in the industry?

MS. SUTHERLAND: Objection.

THE WITNESS: Absolutely.

BY MR. GOSS:

Q. I'm handing you what's been marked as Exhibit 28.

(Exhibit Number 28 was marked for identification.)

BY MR. GOSS:

Q. Is that a document that you reviewed from Ethicon's files?

A. Yes, it is.

Q. Is this a document that you relied upon in forming your opinions that you're giving today?

A. Yes, it is.

Q. And this is another one of those two-page emails. It appears to be -- it

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appears to involve, at the bottom, Dan Smith, who we just talked about; right?

A. Yes.

Q. Janice Burns, who we just talked about as well?

A. Yes.

Q. Charlotte Owens, who appears to be the worldwide medical director --

A. Yes.

Q. -- for Gynecare, a division of Ethicon?

A. That's correct.

Q. Is that a high position?

A. Yes.

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. And it attaches a letter in the back or an email, I guess, from Steve Bell.

Do you see that?

A. I do.

Q. And it says, "Dear All, As more and more customers now move to TVT Blue and TVT-O with blue mesh, you may sometimes hear 'I can see small blue pieces come off the mesh! What's wrong?'"

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Do you see that?
A. I do.
Q. And I want to focus on the third sentence there, the third element there. It says, "Reassure your doctors" -- and, by the way, Steve Bell is director of marketing; right?
A. Yes, for Europe.
Q. And he's saying, "Reassure your doctors that this is part of the success of TVT. The way we have cut the mesh makes the edges softer, and we feel that this has been a crucial success factor in TVT. Reassure them that Prolene has proven to be inert, and there are hundreds of papers going back 25 years to reinforce this point. These particles will not cause any problem."
What I want to focus on is the statement "Reassure them that Prolene has proven to be inert, and there are hundreds of papers going back 25 years to reinforce this point."
Is that statement -- you've reviewed the literature in that regard, have you not?

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A. Yes, I have.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Is that statement true?
MS. SUTHERLAND: Objection.
THE WITNESS: No, it is not.
BY MR. GOSS:
Q. Is it even close to true?
A. No.
MS. SUTHERLAND: Objection.
THE WITNESS: There are certainly papers, but the fact that it's inert, that is definitely not true.
BY MR. GOSS:
Q. Let me ask you, the Global Harmonization Task Force says -- let me refer you to the clinical evaluation.
A. Yes.
Q. Let me refer you to page 4 of 28.
A. Yes.
Q. And, again, just to back up a little bit for the jury, the Global Harmonization Task Force document are documents that you say provide the standard of care for this industry.

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MS. SUTHERLAND: Objection.
THE WITNESS: They're the international globally accepted standard of care, yes.
BY MR. GOSS:
Q. Okay. Is there any debate about that?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
///
BY MR. GOSS:
Q. Okay. Let me -- under "Why is Clinical Evaluation Important," it says, the last sentence of the first paragraph there, "That any claims made about the device's performance and safety should be supported by suitable evidence."
Do you see that?
A. Yes.
Q. The statement that Steve bell is telling his marketing people to say to doctors, does that violate that provision of the Global Harmonization Task Force?
MS. SUTHERLAND: Objection.
THE WITNESS: It certainly

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does.
BY MR. GOSS:
Q. Is it supported by suitable evidence?
A. No, it is not.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Okay. And is that a violation of the standard of care?
A. Yes, it is.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Okay. And then just to close up on this, the email on the first page, Dan Smith, again, is telling Charlotte Owens in the last sentence there, "There's been some customer questions raised about the blue particles again, the same as when it was released in the States."
Is that important in forming your opinion?
A. Yes, it is.
Q. Why is that?
A. This is an ongoing problem, and, in fact, there is other documentation as well

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and testimony that says this is a product defect, and the company is aware it's ongoing but yet has not addressed it.
Q. As of the 2004 time period here, the time period of these emails, have you seen anything in Ethicon's files where it's done a clinical test on particle loss?
A. No. None.
Q. And whether or not it's safe?
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
No testing.
BY MR. GOSS:
Q. Okay. Would a reasonable, prudent manufacturer at this time have begun clinical testing, at least by this time, to determine whether or not this particle loss was an issue?
A. If they were going to maintain this on the market, absolutely.
THE VIDEOGRAPHER: Can we go off for 10 seconds?
MR. GOSS: Sure.
THE VIDEOGRAPHER: With the approval of counsel, I'm going off the

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record. The time is approximately 7:08 p.m.
(Recess taken from 7:08 p.m. to 7:10 p.m.)
THE VIDEOGRAPHER: With the approval of counsel, back on the record. The time is approximately 7:10 p.m.
BY MR. GOSS:
Q. I'm going to hand you two documents that I believe go together marked as Exhibits 29 and 30.
(Exhibit Numbers 29 and 30 were marked for identification.)
BY MR. GOSS:
Q. Have you seen those documents before?
A. Yes, I certainly have.
Q. Are those documents that came out of Ethicon's files?
A. Yes.
Q. Are these documents that you reviewed and relied upon in forming your opinions?
A. Yes, they are.
Q. And this appears to be an email

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string involving, among others, David Menneret who is a complaint investigator and regulatory contact for Ethicon; is that right?
A. That's correct.
Q. It also involves -- if you look at the front page, Dan Smith is involved.
Does this look like the TVT people?
A. Yes.
Q. Okay. And the first document, Exhibit 29, essentially encloses the exhibit -- the letter that's marked as Exhibit 30; is that right?
A. I'm sorry. Could you reask that?
Q. The first document, Exhibit 29, is really enclosing and transferring the letter marked as Exhibit 30; right?
A. Yes, that's correct.
Q. And what is Exhibit 30?
A. Exhibit 30 is a letter from a Dr. Eberhard who has been a major user, actually an important customer in Switzerland, important user of Ethicon's products -- mesh products.
Q. I believe on the second page of

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Exhibit 29, they describe him as an opinion leader?
A. Yes.
Q. It says, on Exhibit 29, "He knows everything about tape, and if we lost him, we lost all."
Do you see that?
A. Yes.
Q. By the way, what's an opinion leader?
A. An opinion leader is, in this case, a doctor who is very well recognized in his field of practice as an authority.
Q. Okay. And so this opinion leader who they describe in the email as someone who knows everything about tape and if we lost him, we lost all, and his letter on Exhibit 30, he states, "Dear Emilie, Please find attached a TVT tape which was used as a demo unit for patients before they have their operation.
"Already at the operation, it is embarrassing to see how the tape is crumbling, but it gets worse if there is a stretch on the tape. It is urgent that

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Johnson & Johnson quickly produce a tape that is solid and weaved. If not, I have the convenience that the doctors will change the tape and will get others. I can't understand that no one will solve that problem for such a long time.

"At the latest, as the tape has become blue, everyone has realized the quality of the tape is terrible." Then he attaches some pictures. And it says the tape needs to be weaved; so it doesn't crumble.

Why is a document like this -- why do you find something like this, if you do, important in their files?

MS. SUTHERLAND: Object to the reading of the document.

THE WITNESS: It's critically important. It's another complaint. The company has gotten now multiple complaints about the fraying of its product from the doctors who are using it. And companies have a responsibility to investigate complaints, to implement corrective and preventive actions as

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appropriate to change the issue, to address the issue, I mean to say, and correct it and study if it's causing safety and efficacy risks.

BY MS. SUTHERLAND:

Q. After this receipt of this letter from this person they've described as one of their opinion leaders, as someone who knows everything about tape in November of 2004, did you see any evidence in the files where the company endeavored to start conducting any clinical trials to see what's going on with this problem?

A. No.

MS. SUTHERLAND: Objection.

BY MS. SUTHERLAND:

Q. Would a reasonable, prudent manufacturer have done that?

MS. SUTHERLAND: Objection.

THE WITNESS: If they were going to maintain this on the market, absolutely.

BY MS. SUTHERLAND:

Q. Continuing to market this product without conducting those tests, is that a

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violation of the standards in the industry as set forth in the documents that we've looked at?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes, it is.

BY MS. SUTHERLAND:

Q. You talked earlier today about a -- some slides or a PowerPoint that Gene Kammerer did.

Do you recall that?

A. Yes, I do.

Q. Where he had done some comparisons of mechanically cut mesh and laser-cut mesh?

A. Yes.

Q. I'm going to hand you what's been marked as Exhibits 31 and 32 and ask you if those were the slides that you were talking about.

(Exhibit Numbers 31 and 32 were marked for identification.)

THE WITNESS: Yes, they are.

BY MR. GOSS:

Q. And were those slides -- did you find those -- were those in Ethicon's files?

A. Yes.

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Q. And was there an email accompanying this that demonstrated that they were done by Gene Kammerer?

A. Yes.

Q. And was he an engineer?

A. Yes.

Q. Okay. Is this -- by the way, that email -- we might as well just so we can get a time frame -- just so we get a time frame, I'll hand you what's been marked as Exhibit 33.

(Exhibit Number 33 was marked for identification.)

BY MR. GOSS:

Q. Just so we get a time frame of when this is being done, is that the email that you found in Ethicon's files where these slides were being shown to people?

A. Yes.

Q. Okay. Again, Gene Kammerer is an engineer?

A. He's an engineering fellow at Ethicon research and development.

Q. What's the date of that email?

A. August 28, 2006.

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Q. And he's sending these to a number of Ethicon people; is that right?
A. Yes, he is.
Q. Now, prior to August 28 of 2006, did you uncover any documents in your investigation where something like this comparison had been done prior to 2006?
MS. SUTHERLAND: Objection.
THE WITNESS: No. I don't recall having seen anything earlier than this of this type of comparison.
BY MR. GOSS:
Q. Okay. So and what is -- now let's move to the slides.
A. Okay.
Q. Okay. What is it that he's doing in Exhibits 31 and 32, just generally?
A. He's taken pictures of laser-cut mesh versus mechanically cut mesh, particularly on stretching.
Q. Okay. Let's look at Exhibit 31. That's the first one; right?
A. Yes.
Q. And does he describe his results there?

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A. Yes, he does.
Q. And generally, what is he saying about the results of this comparison that he's done, this engineering fellow has done who works for Ethicon?
MS. SUTHERLAND: Objection.
THE WITNESS: He's stretched the samples of both the laser-cut and the mechanically cut mesh to 50 percent elongation then let them relax. And the mechanically cut mesh shows, as I was talking about earlier, the degradation of the structure of the mesh in certain areas because of particle loss, whereas the laser-cut mesh does not show that same degradation of the structure of the mesh, and no particles -- or nearly no particles haven been lost, as he terms it.
BY MR. GOSS:
Q. In that third paragraph, he discusses roping. Tell the jury what roping is.
A. It's a stretching and narrowing of the mesh so that it loses its structure and

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it ropes, and it can rope underneath -- you know, the idea of the sling, the tape is that it fits under the urethra to support the urethra to prevent stress urinary incontinence, and that roping can affect effectiveness as well as safety.
Q. And what does he conclude with respect to mechanically cut mesh versus laser-cut mesh as to roping?
A. That the mechanically cut mesh ropes, and the roping does not occur with the laser-cut mesh.
Q. And what did he -- what did he conclude about particle loss with respect to mechanically cut mesh versus laser-cut mesh?
A. There's significant particle loss with the mechanically cut mesh where, by contrast, the laser-cut mesh, there's either no particle lost or almost no particles lost.
Q. And let's go to the third page of that first exhibit where it's a side-by-side slide.
Do you see that?
A. Yes, I do.

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Q. And tell me what's going on here.
A. This is a picture that shows what he described. It's a picture of the mechanically cut mesh that's been relaxed after it's been pulled 50 percent elongation, and the same pictures of the laser-cut mesh after it's been treated in the same way.
And one can see on the edges of the mechanically cut mesh how the weave that has been -- the structure has been lost. You can see the particles that have been lost in the photographic field, and you can see the narrowing.
And by contrast, you can see on the laser-cut mesh, you don't see the particles in the photographic field because there weren't the particles lost, and you can see, although there may be some narrowing from the stretching, certainly not as significant and that the mesh structure has remained intact.
Q. And then the next page of that slide he discusses a -- it's entitled "Description of Side-By-Side Views."

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A. Yes.
Q. And what does he conclude?
MS. SUTHERLAND: Objection.
THE WITNESS: What I was just describing that no particles can be seen lost in the laser-cut mesh and that the structure of the laser-cut mesh remains intact so that the integrity of the mesh across the full width of the sample still holds in contrast to the mechanically cut mesh where the integrity of that mesh, the structure has been lost, and there's a degradation of the outer wale of the knit.
BY MR. GOSS:
Q. Let's go to the next exhibit, the second part of the slide.
And what's that exhibit number?
A. 32.
Q. Let's go to Exhibit 32. And just go to the end. First of all, on Exhibit 32, does he continue to conduct elongation testing and some things you've described?
A. Yes.
Q. And then what is his summary there

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at the back page of Exhibit 32?
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. What does he conclude?
A. He concludes "That the laser-cut mesh resists degradation of the knit construction, resists particle loss and permanent narrowing better than the mechanically cut mesh," and although there's some variation in the results and some of the mechanically cut mesh held up better than others, overall, the finding holds true across all the tested articles that their laser-cut mesh provides more consistent test results, good results.
Q. Is roping an adverse risk?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Okay. And we've talked about the standards?
A. Yes.
Q. Global Harmonization Task Force standards?
A. Yes.

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Q. And about reducing risk.
A. Yes.
Q. Based upon those standards and based upon the documents that you've seen in Ethicon's files, what would a reasonable, prudent manufacturer have done?
MS. SUTHERLAND: Objection.
THE WITNESS: They would have done the appropriate testing to -- first of all, they would, as I have mentioned, on the mechanically cut mesh, they should have implemented corrective and preventive action. Looking at laser-cut mesh could be one of those techniques, methods that they use to do that.
But then, although they showed here that the laser-cut mesh resisted the same degradation, then they would also need to evaluate the potential impact on safety and effectiveness of the laser-cut mesh as well before they would implement it.
BY MR. GOSS:
Q. Okay. So here we are again August of 2006. Have you seen any documents in the

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company's files where they have even suggested that they should even implement any clinical testing?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. Would a reasonable and prudent manufacturer at that time -- at least at that time have conducted clinical tests?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Okay. Let's go to -- I'll hand you what's been marked as Exhibit 34.
(Exhibit Number 34 was marked for identification.)
BY MR. GOSS:
Q. And ask you is that a document from Ethicon's files that you reviewed?
A. Yes, it is.
Q. Is it a document that you relied upon in forming your opinions?
A. Yes, it is.
Q. And it appears to be another one of these -- this email from Alison London

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Brown, who the document describes is a product director, incontinence and pelvic floor repair, Gynecare worldwide division of Ethicon.

Are you familiar with who Alison London Brown is?

A. Yes, I am.

Q. And it's -- appears to be a to a number of marketing people. Isn't Kevin Mahar in marketing?

A. To the best of my recollection, yes.

Q. All right. And so what I really want to ask you about is the second paragraph there. I want you to explain to the jury that second paragraph and if it's important.

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. "The basic story here is that the current mesh, MCM" -- is that mechanically cut mesh?

A. Yes.

Q. "Is perceived by some physicians as inferior, and we do get a high number of

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complaints on linting and roping" -- roping is what we just talked about; right?

A. Yes.

Q. And they're getting a high number of complaints?

A. That's correct.

Q. "Mesh particles falling off and the material stretching to the point of being a string. The new material would dramatically reduce the incident of linting and should all but eliminate the roping as it stays nice it flat."

And they're talking about laser-cut mesh; is that right?

A. Yes.

Q. Okay. So tell us the importance of that --

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. -- if any.

A. Just that part?

Q. Yeah, what we just read.

A. Basically, she's saying that -- reiterating their knowledge of the numbers of complaints that they have gotten because

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of the issues with the mechanically cut mesh losing particles and stretching to the point of even being a string so that it ropes, and the laser-cut material doesn't have those same issues.

Q. Do you remember when we talked about the Global Harmonization Task Force standards?

A. Yes.

Q. Where we talked about minimizing risk, if possible?

A. Yes.

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. Applying that standard -- applying that standard to this information, what would a reasonable and prudent manufacturer do?

MS. SUTHERLAND: Objection.

THE WITNESS: They would do the appropriate testing. They would do the appropriate testing to -- of the laser-cut mesh to substantiate that the laser-cut mesh, by the way it's cut, even though it doesn't lose the

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structural integrity as the mechanically cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in its characteristics as a result of cutting with the laser don't affect safety and performance.

///

BY MR. GOSS:

Q. And let's get our timing back in our heads here. Jennifer Ramirez had her surgery in September of 2010 --

A. That's correct.

Q. -- right?

And she got mechanically cut mesh; is that right?

A. Yes, she did.

Q. And at the time of that surgery, was laser-cut mesh available for her?

A. Yes, it was available. It became available in fourth quarter of 2006.

Q. And mechanically cut mesh was still on the market?

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A. Yes, it was.
Q. And had Ethicon received a number of similar complaints to the ones that you just discussed, these last couple that we just discussed?
MS. SUTHERLAND: Objection.
THE WITNESS: Absolutely, yes.
BY MR. GOSS:
Q. And when Jennifer got her mechanically cut mesh in September of 2010, even by that time, had the company done any clinical testing to determine whether there was a difference in mechanically cut mesh versus laser-cut mesh?
MS. SUTHERLAND: Objection.
THE WITNESS: No. No testing for that, and no testing to determine if the linting and the fraying and the roping affected safety and performance, although they maintained the mechanically cut mesh on the market.
BY MR. GOSS:
Q. And some of the complaints are complaints that the material was stretching to the point of being a string?

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MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Have you ever heard of the term "bow stringing"?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Have you ever heard that in connection with the problems that Jennifer Ramirez has?
A. Yes, I have.
Q. And was Ethicon receiving complaints about that type of problem back as early as May of 2005?
A. Yes.
Q. Okay. I'm going to hand you what's been marked as Exhibit 35.
A. Thank you.
(Exhibit Number 35 was marked for identification.)
BY MR. GOSS:
Q. And this document is entitled "Clinical Expert Report."
Is that a document that came from

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Ethicon's files that you reviewed?
A. Yes, it is.
Q. Is it a document that formed the basis of your opinions in this case?
A. Yes, it is.
Q. Who is Martin Weisberg?
A. He's the senior medical director -- at this time, he was senior medical director at Ethicon.
Q. And this document is dated April 18, 2006?
A. That's correct.
Q. What's a clinical expert report?
A. It's essentially -- we talked earlier -- we referred to the GHTF document on clinical evaluation, and it's basically a clinical evaluation that's been undertaken by Dr. Martin Weisberg, who we just talked about, and also a Dr. David Robinson, who is a medical director at Ethicon, to assess clinically the laser-cut mesh.
Q. So this document, is this sometimes referred to as a CER?
A. Yes.
Q. Certified expert report?

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A. Yes.
Q. So the CER was intended to assess laser-cut mesh?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Okay. Well, did they endeavor to assess laser-cut mesh?
A. The only testing that was done to assess the laser-cut mesh was benchtop testing, and it was not done with laser-cut mesh. It was done with ultrasonically -- let's see. Some of the testing was done with ultrasonically-cut mesh, but there was no testing in animals, no testing in humans.
Q. What do you mean by "benchtop testing"?
A. Like the pictures we -- for example, like the pictures we were just looking at where there was -- it was a tensile strength test to look at the elongation of the mesh. That would be a type of benchtop testing, burst strength, measurement of pore size, measurement of various characteristics of the mesh on a

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benchtop laboratory setting.
Q. It has nothing to do with animal testing?
A. No.
Q. Has nothing to do with human testing?
A. Not this type of testing, no.
Q. At this time -- let's talk about the background section there. Does it describe for us the reason they're doing this testing?
A. Yes.
Q. Explain to the jury why they're doing -- why they purport to be doing the testing.
MS. SUTHERLAND: Objection.
THE WITNESS: Their rationale for doing this is to switch from mechanically cut as a response to, as they term it, customer needs, that customers expressed a desire for a mesh with smoother edges rather than edges with the ends of individual fibers exposed, which is a reference to the fraying, and also they note that

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customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh.
BY MR. GOSS:
Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss?
A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh.
Q. Did they ever, at this time or any time after, do any clinical testing to determine whether losing particle loss -- more particle loss was significant?
A. No.
Q. Would a reasonable and prudent manufacturer have done that?
MS. SUTHERLAND: Objection.
THE WITNESS: Absolutely.
BY MR. GOSS:
Q. They note that this study was performed -- this is on page 4 -- that this study was performed on ultrasonic-cut mesh and not laser-cut mesh; is that right?
A. That's what this document states,

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yes.
Q. Why would a company, if you know, why would they test ultrasound mesh instead of laser-cut mesh if they're trying to determine that the scope -- as they say on the front page, "The project scope applies to Prolene mesh laser cutting," and yet they don't test laser cutting.
MS. SUTHERLAND: Objection.
///
BY MR. GOSS:
Q. Do you know any plausible reason why they did that that you've uncovered in their files?
A. No. There was -- this was inappropriate.
Q. Did you find anything in their files that said, "Hey, we're out of laser-cut mesh. Let's use some ultrasonic mesh"?
A. No.
Q. Based upon your 40-plus years of experience and your 40-plus years of experience where you've designed testing, clinical testing, benchmark testing, and

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advised companies on the appropriate testing to do for a product, would that in any way be appropriate testing for this product?
MS. SUTHERLAND: Objection.
THE WITNESS: Absolutely not.
BY MR. GOSS:
Q. And to rely on testing like that, would it be a violation of the standard of care?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it would.
BY MR. GOSS:
Q. Okay. I'm handing you what's been marked as Exhibit 36.
(Exhibit Number 36 was marked for identification.)
BY MR. GOSS:
Q. Is that a document that you found in Ethicon's files?
A. Yes, it is.
Q. Is it a document that you reviewed?
A. Yes, it is.
Q. Is it a document you relied upon in forming your opinions in this case?
A. Yes, it is.

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Q. And is it an Ethicon document?
A. Yes.
Q. And it's another one of these string emails, is it not?
A. Yes.
Q. Actually, I guess, it's just --
A. It's a couple.
Q. Just a couple. And it involves Gene Kammerer. We've talked about him?
A. Yes.
Q. He's an engineering fellow?
A. Correct.
Q. He's the one that did the slides we were talking about?
A. That's correct.
Q. And then it also has Sunny Rha, who's -- this identifies as operations integrations, Ethicon, a Johnson & Johnson Company; is that right?
A. Yes.
Q. I don't want to spend a lot of time on this, but I simply want to ask: What are they talking about here at the beginning of this about the French standards of particle loss? Explain to the jury what this

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discussion entailed.
MS. SUTHERLAND: Objection.
THE WITNESS: That there's a new French standard test method for determining particle loss, and the difference between the TVT and the competitors in that test is significant, particularly almost tenfold more for TVT particle loss with 8 percent of the mesh falling off.
BY MR. GOSS:
Q. Is that mechanically cut mesh?
A. Yes.
Q. Okay. And the year of that is June, 2006; is that right?
A. Yes.
Q. Why is that document important, if at all, in your opinion?
MS. SUTHERLAND: Objection.
THE WITNESS: It documents that 8 percent of the mesh falls off, and that's -- so you have 8 percent of particles that potentially are loose, either in the package or in the patient, with no testing to determine that with 8

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percent of the mesh lost and the structural integrity of that mesh affected by the particle loss, how that impacts both safety and effectiveness when implanted.
BY MR. GOSS:
Q. I'm going to hand you what's been marked as Exhibit 37.
A. Thank you.
///
(Exhibit Number 37 was marked for identification.)
BY MR. GOSS:
Q. Is that a document that came from Ethicon's files that you reviewed?
A. Yes, it is.
Q. Is it a document that you relied upon in forming your opinions in this case?
A. Yes, it is.
Q. And it's dated November 18 of 2003?
A. Yes.
Q. Again, this is a document cc'ing Gene Kammerer. We talked about him?
A. Right.
Q. We talked about Brian Luscombe.

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A. Yes.
Q. It's from Marty Weisberg, and he is the senior medical director of Gynecare?
A. That's correct.
Q. I just want you to focus on the first paragraph of that document and tell me whether or not this is a document that was important to your opinions and, if so, why?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes. This document is important to my opinions. It documents that as far back as 2003, November, 2003, actually prior to the marketing of the TVT-O, that the company had received a recorded total of 58 complaints of fraying, and it also states that the fraying is inherent in the design and construction of the product and that any tension applied exacerbates, makes that loss of integrity and fraying worse, and that when the fraying happens, just as we've been talking about, several things occur.
The mesh elongates in places

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and narrows in places, and the small particles may break off.
BY MR. GOSS:
Q. Again, is that important to you because it put the company on notice as to problems?
MS. SUTHERLAND: Objection.
THE WITNESS: Absolutely.
BY MR. GOSS:
Q. Does that put the company on notice as to any problems?
A. Absolutely, it does.
MS. SUTHERLAND: Quit fixing your questions.
BY MR. GOSS:
Q. Okay. Let me hand you what's been marked as Exhibit 38.
(Exhibit Number 38 was marked for identification.)
BY MR. GOSS:
Q. Do you recognize this document?
A. Yes, I do.
Q. Is this a document that came out of Ethicon's files?
A. Yes, it is.

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Q. Is it a document that you relied upon in forming your opinions in this case?
A. Yes, it is.
Q. It appears to be a product pointer. Is it something that seems to be a marketing document?
A. Yes.
Q. Dated June 26, 2006?
A. That's correct.
Q. And I don't want to spend a long time on this, but let's just -- is this something that's directed to the sales force?
A. Yes.
Q. And what's going on here?
A. The company is going to market the laser-cut mesh, but they are also going to continue to have the mechanically cut mesh on the market as well.
And so they're advising -- they're advising with regard to that and providing the rationale for why they're going to maintain both the mechanically cut and the laser-cut meshes on the market.
Q. What did they say about particle

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loss and potential for mesh fraying?
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. About third paragraph down in bold.
A. Oh, that part. Sorry. I wasn't sure which part you were referencing.
That the laser-cut mesh will be available for customers who are concerned about particle loss and fraying with the mechanically cut mesh.
Q. It states, "We decided to explore the impact of cutting our present TVT products on the laser cutter. We found by doing so, we reduced particulate loss as well as the potential for mesh fraying."
Is that important?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Why is that important?
A. Again, and this is just another document that discusses what the other documents that we've been reviewing addresses that the company is aware that they have a methodology to reduce that

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particle loss and reduce fraying.
Q. As of June 26, 2006, have they still not conducted any clinical tests?
A. They still have not.
Q. In fact, I think on the -- they say, "As a result of the laser-cutting process, the edges of the mesh will appear and may feel slightly different upon stretching. We have conducted several bench tests."
Are those the tests we've been talking about?
A. Yes.
Q. Again, what's the difference between bench test and clinical test?
A. Well, bench testing is done in a laboratory setting on a benchtop. It's things like stretching the mesh and the elongation tests that we talked about. Tests of the physical properties, the mechanical properties of the mesh.
Q. Never been tested -- they weren't testing it in a woman's pelvis, were they?
A. No, they were not.
Q. And the products on the market at

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that time, 2006, never been tested in a woman's pelvis; is that right?
MS. SUTHERLAND: Objection.
THE WITNESS: That's correct.
BY MR. GOSS:
Q. Laser-cut mesh, at this point, before it's been launched, has it been tested in a woman's pelvis?
A. Can you repeat your prior question? That's what I understood it to be.
Q. They're about to launch laser-cut mesh.
A. Yes.
Q. At that point, has it even been tested in a woman's pelvis?
A. No. No.
Q. Okay. And I believe when I showed you early on some of the testimony that you had reviewed, Piet Hinoul was somebody that you had reviewed their testimony?
A. Yes.
(Exhibit Number 39 was marked for identification.)
BY MR. GOSS:
Q. I'm handing you what's been marked

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as Exhibit 39 entitled "Trial Proceedings."
And this, on the front page, identified -- is identified as trial proceedings from the Linda Batiste trial in Dallas, Texas.
Are you familiar with that trial?
A. I am.
Q. Did you testify at that trial?
A. Yes, I did.
Q. And it's dated March 27, 2014.
Do you recognize this as the testimony of Piet Hinoul?
A. Yes, I do.
Q. In fact, let me -- I'm just going to go ahead -- I'm not going to use it, but I want to put it in the record.
(Exhibit Number 40 was marked for identification.)
BY MR. GOSS:
Q. I'm going to hand you Exhibit 40, and I'll represent to you that Exhibit 40 is the trial testimony of Piet Hinoul, and what Exhibit 39 is, if you want to assure yourself of it, is some excerpts taken from that trial testimony.

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Do you want me to help you?
A. I was just looking for the start of his testimony. Do you know what page number it starts? Based on my prior review, it looks to be the same, but I will verify.
Q. On page 65, there is the total transcript, and you will see the excerpt that I've handed you is an excerpt from there.
A. Yes.
Q. So reading from page 65 of that transcript, and I'd like for you to read to yourself page 65, lines 12, through page 66, line 12, and let me know if that's testimony that you reviewed in forming your opinions in this case and whether it's something you relied upon.
A. Yes, I did.
Q. Okay. And this is March -- this testimony is March 27, 2014?
A. Correct.
Q. Question -- this is Piet Hinoul. He's medical director; right?
A. Yes.
Q. Worldwide medical director?

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A. Yes, he was.
Q. For Ethicon.
A. Yes.
Q. Pretty high up.
A. Very much so.
Q. "And that was the story that was told to doctors, correct, that they're identical, essentially" -- that they're identical, essentially; right?"
Talking about mechanically cut versus laser cut; right?
A. Yes.
Q. "And you told doctors that one won't cause any more medical problems than the other; right?
"ANSWER: And that's what we still say today, yes.
"And there's never been a study, even in the literature, there has never been a study that specifically looked at the mechanically cut mesh versus the laser-cut mesh to determine whether or not one is more dangerous than the others; correct?
"ANSWER: Correct?
"Of all those thousands of doctors

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that you're paying, many of which you're paying to do studies, never any of them, you never asked any of them to do that study; correct?

"ANSWER: You say a lot of the things in your sentence here.

"QUESTION: Have you ever asked any doctor, any paid consultant that you're asking to do studies, to do a study specifically looking whether or not there is more injuries to women with mechanically cut mesh versus laser-cut mesh? Have you ever asked anybody to do that?

"We have not."

Did you rely upon that testimony in forming your opinions?

A. Yes, I did.

MS. SUTHERLAND: Objection.

BY MR. GOSS:

Q. And what's your opinion about that testimony?

MS. SUTHERLAND: Well, objection.

THE WITNESS: There was never any testing done. That's a violation of

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the standard of care. Testing should have been long done long before this.

BY MR. GOSS:

Q. As of March 2014, still hadn't done any testing?

A. Still hadn't done any. Should have been done prior to -- prior to launch.

Q. What should have been done prior to launch?

A. Clinical testing should have been done prior to launch of the laser-cut mesh, but when they first became aware of the problems with the mechanically cut mesh, they should also have done clinical testing.

To determine if they were going to maintain that on the market, they should have done clinical testing to determine the impact on safety and effectiveness.

Q. Okay. So we've analyzed these documents where is it safe to say -- is it fair to say that we've analyzed some documents that have put the company on notice or at least advised the company that there may be more particle loss and more fraying with mechanically cut mesh than

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laser-cut mesh?

MS. SUTHERLAND: Objection.

THE WITNESS: Definitely, yes.

BY MR. GOSS:

Q. Okay. Did your review and investigation of Ethicon's files, did you find any documents or any PowerPoints or anything or any emails that reflected why Ethicon kept mechanically cut mesh on the market instead of just selling laser-cut mesh?

MS. SUTHERLAND: Objection.

THE WITNESS: Yes, I did.

BY MR. GOSS:

Q. And what did those documents reflect?

A. The TVT was the first polypropylene sling kit that was on the market and had been on the market since 1998. The company had clinical data from the inventor and associates of the inventor dating back to 1996 to 1998 on the product.

Compared to other meshes that were on the market, they had what they considered a competitive advantage because they could

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claim having clinical data on the TVT retropubic product dating back to the late 1990s, and they didn't want to lose the advantage of that competitive -- that competitive clinical data. Or that clinical data that they felt was a clinical advantage.

Q. Clinical history?

A. Yes. Clinical edge.

///

(Exhibit Number 41 was marked for identification.)

BY MR. GOSS:

Q. Okay. I'm going to hand you what's been marked as Exhibit 41.

A. Thank you.

Q. Is this a document that came from Ethicon's files that you reviewed?

A. Yes, it is.

Q. Is it a document you relied upon in forming your opinions in this case?

A. Yes.

Q. And it's from Allison London Brown. Who is Allison London Brown? I believe she's a product director?

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A. Yes.
Q. To Dan Smith, who we talked about is an engineer.
A. Correct.
Q. Was he project lead?
A. Yes.
Q. And it's "Mechanical-Cut Versus Laser-Cut Mesh Rationale." That's what we were just talking about, wasn't it, what was the reasoning, what was the rationale?
A. That's correct.
Q. Okay. And let's go about halfway down that document. Do you see where it says, "Additionally," and this is Allison London Brown giving the rationale.
A. Yes.
Q. "Additionally, the mechanically cut TVT mesh can be stretched to deformation, creating a rope if not placed properly."
We've seen other documents about roping?
A. Yes, we have.
Q. Okay. "Some physicians perceived could irritate/damage the urethra, as competition honed in, this aspect of the

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Gynecare TVT product."
It says, "In order to alleviate concerns/meet customers needs, the team identified two corrections."
One talks about the sheath. But the second one says, "The use of laser cutting for processing which minimized particulate loss as the material was somewhat melted as it was cut, thus keeping mostly cut loops intact."
Is that consistent with the other documents you've seen?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
BY MR. GOSS:
Q. And why is that important?
MS. SUTHERLAND: Objection.
THE WITNESS: That, again, is a document -- another document that substantiates that they knew that there was an issue with mechanically cut mesh. They knew that laser cutting mesh minimized the particle loss and that that would alleviate the concerns of some customers who were concerned about

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fraying and roping.
BY MR. GOSS:
Q. If a manufacturer believed that mechanically cut mesh -- if they believed that it caused roping, and that manufacturer believed that laser-cut mesh eliminated roping, what do the safety principles say they should do?
MS. SUTHERLAND: Objection.
THE WITNESS: They should validate through clinical testing the laser-cut mesh to assure that the difference in characteristics in the laser-cut mesh versus the mechanically cut mesh didn't create safety and effectiveness issue and move to market.
Assuming safety and effectiveness was demonstrated, moved towards marketing the laser cut and discontinuing the mechanically cut.
BY MR. GOSS:
Q. Okay. Then under the second point there, I believe, this relates to what you were testifying about, the clinical data and preserving the clinical data. They say, "In

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order to continue to claim" -- Allison London Brown says, "In order to continue to claim the use of seven-year data in all clinical studies, the MCM and LCM needed to show similar properties with physical properties being used as a proxy for the clinical needs."
What does that mean?
MS. SUTHERLAND: Objection.
THE WITNESS: It means that they made the determination -- they wanted to continue to use the clinical data that they had dating back to the late 1990s on the mechanically cut mesh, which was used in the initial TVT product, and in order to do that, they made the determination that they would assess physical properties, and if they were similar enough based on Ethicon's determination of what similar meant, then they would use that instead of doing clinical testing.
BY MR. GOSS:
Q. If Ethicon admitted that laser-cut mesh was superior to mechanically cut mesh

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and offered only laser-cut mesh, is this saying that they would not be able to rely upon that seven-year data that they had collected?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. And if they were unable to rely on the seven-year data that they have collected, what would be the effect of that?
MS. SUTHERLAND: Objection.
THE WITNESS: Well, their concern is if they can't show similarity for the laser-cut mesh, similar enough that they can maintain the use of that seven-year data, that they lose that competitive advantage because other polypropylene mesh slings that were on the market by this time didn't have that old data.
So if you look at some of the documents we discussed earlier today, both patient labeling, promotional labeling, as I recall as I sit here today, they discuss the long-term data.

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They reference the data that goes back to the late 1990s, and so the company relied on that as a competitive advantage.
BY MR. GOSS:
Q. If they admitted that laser-cut mesh was different and better than mechanically cut mesh, could they continue to rely on that data?
MS. SUTHERLAND: Objection.
THE WITNESS: No. They would have to do some kind of testing to assess whether or not they could rely on that data. It would not be the same.
BY MR. GOSS:
Q. And would that cost money?
A. Yes.
Q. Would that cost time?
A. Yes.
Q. Would that cost profits?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Would that allow their competitors to gain a competitive edge over them?

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MS. SUTHERLAND: Objection.
THE WITNESS: Yes. That was their concern.
BY MR. GOSS:
Q. Should a company ever -- strike that.
Should a device manufacturer ever put profits over safety?
MS. SUTHERLAND: Objection.
THE WITNESS: Never.
BY MR. GOSS:
Q. Is that a violation of the standard of care?
THE WITNESS: Definitely.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Is that a violation of the safety principles that we discussed today?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
MR. GOSS: Let me go for about another ten minutes and that will be a good stopping point. Okay? Not forever but just a break. But we've made good time, and I'm going to cut a lot out of

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this.
MS. SUTHERLAND: Obviously, I can't leave.
MR. GOSS: I'm going to ask the court reporter. You doing fine? You need a break here in about ten minutes?
THE REPORTER: Yeah, about ten minutes.
MR. GOSS: Can you hold out ten more minutes?
BY MR. GOSS:
Q. Let me shift gears a little bit. We've discussed this problem that existed -- well, there were some discussions internally that we've identified about particle loss; right?
A. Yes.
Q. And particle loss with mechanically cut mesh; right?
A. Correct.
Q. Gene Kammerer compared particle loss with mechanically cut mesh and laser-cut mesh?
A. That's correct.
MS. SUTHERLAND: Objection.

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BY MR. GOSS:
Q. Now, over and above that particle loss issue that was being discussed within the company, was there an additional issue relating to particle loss with respect to the specific lot of mesh that Jennifer Ramirez received?
A. Yes, there was.
Q. What was that issue?
A. The company received two complaints on that specific lot of particle loss.
(Exhibit Number 42 was marked for identification.)
BY MR. GOSS:
Q. Okay. Let me hand you what's been marked as Exhibit 42.
Is this a document that came from Ethicon's files?
A. Yes, it is.
Q. Is this a document that you reviewed with respect to your opinions?
A. Yes, it is.
Q. Is it a document that you relied upon with respect to your opinions?
A. Yes, it is.

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Q. And this document is entitled "Particles in TVT-O Blisters"?
A. Yes.
Q. The second page of Exhibit 42 is "TVT-O Complaints"?
A. Yes.
Q. It says, "Since July, 2010, six complaints have been recorded for the following issue: Foreign matter in TVT-O blisters."
And then it lists the complaints; right?
A. Yes.
Q. And it lists the product code; right?
A. Yes.
Q. And is that 810081, is that the same product code that was on the sticker that we discussed earlier today for Jennifer's lot?
A. Yes.
Q. Okay. So she -- just so I'm clear, they were receiving -- this document says they were receiving complaints about a specific batch; is that right?

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MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Specific product code?
A. For a specific product code, yes.
Q. And that included Jennifer's?
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Or did that include Jennifer's?
A. For the product code. This was the product code for mechanically cut mesh.
Q. Go to page 3. And this is a PowerPoint we're looking at, is it not?
A. Yes.
Q. And it says, on the second sentence there on page 3, "The presence of Prolene particles in the blister is common for a manual code compared to laser code."
Why is that important?
MS. SUTHERLAND: Objection.
THE WITNESS: That is stating what we've been discussing that the manually-cut mesh has particle loss and structural integrity degradation where the laser code does not have those same -- the laser-cut product does not

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have those same issues.
BY MR. GOSS:
Q. Okay. Let me hand you what's been marked as Exhibit 43.
(Exhibit Number 43 was marked for identification.)
BY MR. GOSS:
Q. And this is another one of those string emails; right?
A. Yes.
Q. And this is an email from -- let's just start in the back, Kathie Chen, who appears to be from J&J in Medical Taiwan; is that right?
A. Yes.
Q. And she is writing an email to Darlene Kyle; right?
A. Yes.
Q. This is dated July 1, 2010?
A. Yes.
Q. Now, Jennifer got her implant September of 2010; right?
A. That's correct.
Q. And this is July 1 of 2010; right?
A. July 5, yes.

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Q. I'm sorry. July 5.
A. Well, there are different dates on here. There's July 1 to July 5.
Q. Couple months before Jennifer's implant?
A. Yes.
Q. And it says, "Dear Darlene. Good day. I've had some quality queries about the product TVT obturator system. Could you please answer it for me. Today our customer found some tiny mesh pieces (about 2 millimeters) in the unopened tyvek box. So they refused to accept the product TVT-O. Could you please let me know why these" -- "why did these tiny mesh pieces fall within the sterile package? Is this product with tiny mesh pieces safe to be used?"
And then the response is -- well, she then writes again -- does she not? -- on the first page following up this email string?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. She's again saying, "We received

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another three cases, same as yesterday"?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. Okay. Then Darlene who she was writing to, and Darlene is, as I understand it, she's an analyst, worldwide consumer customer quality. Does that seem right to you? It's not on here, but I think there's some emails we're about to see.
A. That would sound right then. I don't recall specifically.
Q. This is a customer quality or product quality issue?
A. Yes, it is a product quality issue.
Q. And so Darlene Kyle writes back to Kathie and she says with respect to these particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."
Is that important?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it is.
BY MR. GOSS:
Q. Why is that important to your

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opinion?
A. It's stating -- essentially it's saying this is a product defect, and the product shouldn't be used.
Q. Did you see anywhere where Ethicon sent any Dear Doctor letter or any Dear Healthcare Provider letter or told anybody on the outside that this is not normal in that product and that the product should not be used?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. Do you see where they did any voluntary recall or even thought about doing a voluntary recall?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. Any discussion of voluntary recall?
A. Nothing that I've ever seen.
Q. Any discussion that you saw in their files of advising doctors or healthcare providers that there may be a problem with one of these lots?

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MS. SUTHERLAND: Objection.
THE WITNESS: No.
BY MR. GOSS:
Q. And, again, this particle loss, what we're talking about here is separate from the particle loss issue that we've been discussing, is it not?
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. I mean, this is about a specific batch now; right?
A. They only use the product code, but they are talking, as best I can tell, they are -- let me just take a moment to look at this. They're talking about the product code for manually-cut mesh, and it appears because it's coming from four cases and one complaint coming from the same hospital. I don't see that it actually gives the --
Q. Well, on the second page, it says code 810081 within the --
A. Right. That's the code for TVT-O.
Q. Okay. Let's move on. Anyway, so they received these complaints; right?
A. Yes.

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MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. I'm going to hand you what's been marked as Exhibit 44.
(Exhibit Number 44 was marked for identification.)
BY MR. GOSS:
Q. Do you recognize that document?
A. Yes, I do.
Q. And is that a document that came from Ethicon's files?
A. Yes, it is.
Q. Is it a document that you relied upon?
A. Yes, it is.
Q. And who's Meng Chen?
A. She is an associate medical director.
Q. And Carolyn Brennan, who appears to be a manager of women's health and urology, worldwide customer quality?
A. Correct.
Q. This, again, is addressing this particle loss issue?
A. Yes, it is.

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MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. And Meng Chen, isn't she an associate medical director?
A. Yes, she is.
Q. And Meng Chen responds -- with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."
Does it -- first of all, did you see anywhere where they did any testing, or there was any analysis done at all to determine that it was remote?
MS. SUTHERLAND: Objection.

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THE WITNESS: No. I did not see any testing.
BY MR. GOSS:
Q. Did you find anything like that in their files?
A. No, I did not.
Q. If there was no such analysis in their files, there was not any such analysis done, to make a statement that it was remote, would that be a violation of the standard in the industry?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it would.
BY MR. GOSS:
Q. Okay. I have two more, and then we can break. I'm handing you what's been marked as Exhibit 45.
A. Thank you.
(Exhibit Number 45 was marked for identification.)
BY MR. GOSS:
Q. This is another one of those email chains.
A. Yes.
Q. So we start from the back. First

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of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?
A. Yes, it is.
Q. Is it a document that you reviewed with respect to your opinions?
A. Yes, it is.
Q. Is it a document that you relied upon in forming your opinions?
A. Yes, it is.
Q. And looks like this is another document involving Darlene Kyle. Remember I said earlier, she was an analyst, worldwide customer quality.
Do you see that on the last page?
A. Yes, I do. Thank you.
Q. And also I see Meng Chen's also copied on these emails. We just talked about her.
A. Correct.
Q. And Shalot Armstrong. She's a manager -- it appears manager -- I think she's a manager in quality systems and compliance.
Do you think that's true?

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A. That sounds right, to the best of my recollection.
Q. Okay. And they're talking about -- if you go to the bottom of page 1, and they ask -- Darlene's asking Carlos Lugo-Ponce -- they're discussing this issue about whether or not it's safe despite small pieces of mesh that are being found in the packaging.
Do you see that?
A. Yes, I do.
Q. And what I want to ask you about is Carlos Lugo-Ponce's response at the top there is "Darlene, First, I recommend a meeting rather than an email chain." And then he talks about at the bottom still needing "a detailed understanding of how this happens in the manufacturing floor, what defect classification this is, and how frequent this is."
He's talking about -- is he talking about the product?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, he is.
BY MR. GOSS:
Q. Is he talking about a

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product-related issue?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. And product performance issue?
A. Yes. Product quality issue.
Q. Okay. And his first sentence there is "First, I recommend a meeting rather than an email chain."
Do you see that?
A. Yes.
Q. Now, after this email -- now we just talked about how we didn't see much going on with respect to where Meng Chen came up with her determination that it was remote.
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. After this email that we're talking about, which is Exhibit 45, where Carlos says let's do meetings, not an email chain, you didn't see much more after that, or did you?
MS. SUTHERLAND: Objection.

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THE WITNESS: No, I have not.
BY MR. GOSS:
Q. Okay. Well, let me -- did the company have a corporate policy regarding careful communications?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes, it did.
(Exhibit Number 46 was marked for identification.)
///
BY MR. GOSS:
Q. I'm handing you what's been marked as Exhibit 46. And is this a document that you reviewed in -- is this a document from Ethicon's files?
A. Yes, it is.
Q. Is this a document that you reviewed in connection with forming your opinions in this case?
A. Yes, it is.
Q. And it's entitled "Introduction to HCC: Key Takeaways and Contacts." And it's talking about mission statement for HCC. By the way, do you know what HCC is?
A. Yes. It stands for healthcare

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compliance.
Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos Lugo said let's not do this in writing?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Let's have meetings?
MS. SUTHERLAND: Objection.
THE WITNESS: Yes.
BY MR. GOSS:
Q. And let me turn you to the Bates stamp 465 at the bottom, the last three numbers are 465.
A. Yes, I have it.
Q. And the careful communications.
Do you see that?
A. Yes, I do.
Q. And it says at the bottom talking about "With regards to electronic communications."
Do you see that?
A. Yes.
Q. "Including email and text

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message" -- let me start over.
"With regards to electronic communications, including email and text messaging, it is important to note no product claims should ever be communicated via email or text messaging."
Do you see that?
A. Yes.
Q. And was what they were talking about in those last emails, were they product claims?
MS. SUTHERLAND: Objection.
THE WITNESS: It relates to product claims, yes.
BY MR. GOSS:
Q. Okay. And the company's policy is this: "Be very cognizant of what you're communicating electronically as any and all forms of communications can be discoverable in a court of law."
Did I read that right?
A. Yes.
MS. SUTHERLAND: Objection.
BY MR. GOSS:
Q. Is that this company's careful

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communication policy?
A. Yes. It's a part of it, yes.
Q. I mean, should a reasonable and prudent manufacturer be concerned about its claims, its product claims and complaints by customers, when handling those complaints, should they be concerned about what's going to be discovered in a court of law?
MS. SUTHERLAND: Objection.
THE WITNESS: The concern should be about addressing the claims and taking the appropriate corrective and preventive actions.
BY MR. GOSS:
Q. And does it appear to you based upon your review of the file and -- that the people in that email chain that they heeded Carlos Lugo's instructions about no more emails?
MS. SUTHERLAND: Objection.
Calls for speculation.
BY MR. GOSS:
Q. Did you see any further emails where they were explaining, for example, how they made the determination that it was

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remote?
MS. SUTHERLAND: Objection.
THE WITNESS: No.
MR. GOSS: Okay. Let's take a break.
THE VIDEOGRAPHER: With the approval of counsel, going off the record. The time is approximately 8:18 p.m.
(Recess taken from 8:18 p.m. to 8:30 p.m.)
MR. GOSS: Let's go on the record.
It's been a long day. I've looked at my notes. I think I probably have time left of almost three hours. I think that I would probably, from the looks of my notes, get close to using all that. It's now -- is it 8:30 our time? 8:30 California time, 10:30 Dallas time.
The court reporter has told me she doesn't have three hours left in her. I think I believe her. And I've talked with the witness.

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Peggy, you can be made available next Thursday or Friday for two-and-a-half hours.
THE WITNESS: That's correct.
MR. GOSS: Okay. I'm available. I understand the doctor's lawyer will make somebody available, and I understand from you, Kari, that you have a firm retreat, but you will try to find coverage.
MS. SUTHERLAND: I will do whatever I can to find coverage. Would you object if, worst-case scenario, we had to have somebody cover it by phone instead of being here?
MR. GOSS: I don't care. That's fine. That's fine. Truthfully, I would do it by phone if I didn't have to hand exhibits.
MS. SUTHERLAND: And as I understand it, you are taking the position that defense counsel is limited to the time that I had left from my six hours, which I think the videographer told me is eight minutes; is that

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correct?
MR. GOSS: Right.
MS. SUTHERLAND: All right. And I would just note an objection to that, that plaintiffs did not cross-notice this deposition. I had no notice that this was going to be a trial deposition. I certainly didn't prepare for a trial cross-exam, and so I would preserve whatever objection might possibly be available to me under Texas law to come back and do a thorough cross-exam of the witness, either me or somebody from the trial team.
MR. GOSS: I note your objection. I don't agree with it under Texas law. We didn't have to cross-notice it. Anyway, we don't have to argue about that. I got your objection.
MS. SUTHERLAND: Yeah. It is what it is. I had my marching orders to get that on the record, and I have.
MR. GOSS: You've got to tell your local -- anyway, we don't need to

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get into that. It's been a long day. Thanks, everybody. I think we all cooperated, and obviously, I'm not passing the witness. We're adjourned.
MS. SUTHERLAND: Right. And as soon as I know which day will work for coverage, I will let everybody know.
MR. GOSS: Okay. Yeah. And just so we're all clear, I don't think -- I'm certain that I'm not going to convince anybody to come take my place.
MS. SUTHERLAND: That's my fear.
MR. GOSS: Obviously, I don't have any problem with switching out lawyers and all that. I understand. Okay. All right. Thank you.
(Whereupon the deposition adjourned at 8:33 p.m.)

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REPORTER'S CERTIFICATE

The undersigned Certified Shorthand Reporter licensed in the State of California does hereby certify:

That the foregoing deposition was taken before me at the time and place therein set forth, at which time the witness was duly sworn by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed, said transcript being a true copy of my shorthand notes thereof.

I further declare that I have no interest in the outcome of the action.

In witness whereof, I have subscribed my name this 30th day of March, 2016.

____
LISA MOSKOWITZ
CSR 10816, RPR, CRR, CLR
NCRA Realtime Systems Administrator

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LAWYER'S NOTES

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